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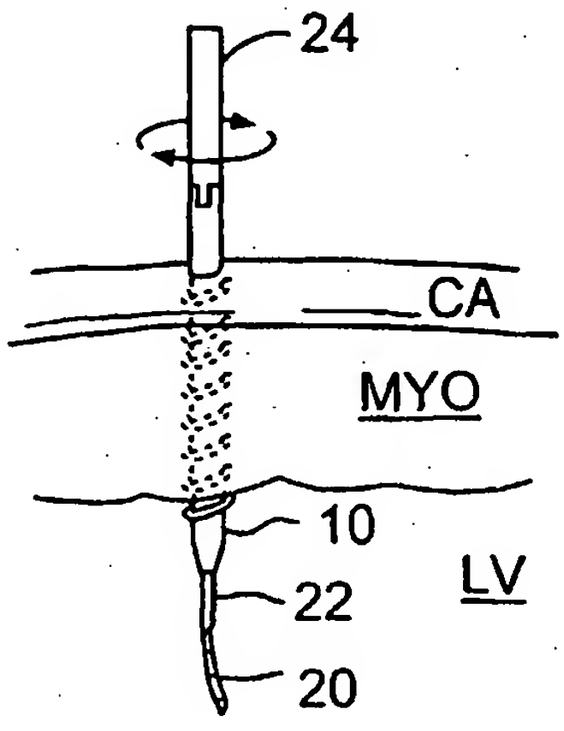
(54) Title: LEFT VENTRICULAR CONDUITS AND METHODS FOR DELIVERY



(57) Abstract: Conduits are provided to direct blood flow from the left ventricle to a coronary artery at a location distal to a blockage in the coronary artery. Threaded and nonthreaded conduits are delivered using a guidewire delivered through the posterior and anterior walls of a coronary artery and into the heart wall. A dilator may be provided over the guidewire into the heart wall, and the conduit delivered over the dilator. An introducer sleeve may be provided over the dilator into the heart wall, the dilator removed, and the conduit delivered through the introducer sleeve. A hollow needle also may be inserted into the posterior and anterior walls of the coronary artery prior to inserting the guidewire. A depth measuring tool may determine the appropriate length of the conduit prior to delivery. The depth measuring tool can include the hollow needle with an acces port on a proximal end of the needle and an opening on the distal end of the needle in flow communication with the access port so that when the needle is inserted through the heart wall and into the heart chamber, blood flow through the opening.

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LEFT VENTRICULAR CONDUITS AND METHODS FOR DELIVERY

Field of the Invention

The present invention relates to an apparatus for bypassing a blocked or stenosed blood vessel segment, and, more particularly, to an apparatus and method for delivering a conduit between the coronary artery and the left ventricle of the heart.

Background of the Invention

Coronary artery disease is a major problem in the U.S. and throughout the world. Coronary arteries as well as other blood vessels frequently become clogged with plaque which, at the very least, can reduce blood and oxygen flow to the heart muscle (myocardium), and may impair the efficiency of the heart's pumping action, and can lead to heart attack (myocardial infarction) and death. In some cases, these coronary arteries can be unblocked through non-invasive techniques such as balloon angioplasty. In more difficult cases, a surgical bypass of the blocked vessel is necessary.

In a coronary bypass operation, one or more venous segments are inserted between the aorta and the coronary artery, or, alternatively, the distal end of an internal mammary artery is anastomosed to the coronary artery at a site distal to the stenosis or occlusion. The inserted venous segments or transplants act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than 500,000 bypass procedures are performed in the U.S. every year.

Such coronary artery bypass graft (CABG) surgery, however, is a very intrusive procedure which is expensive, time-consuming, and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and that the patient be placed on a heart-lung bypass pump so that the heart can be operated on while not beating. A saphenous vein graft is harvested from the patient's leg, another highly invasive procedure, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence are prolonged. Furthermore, many patients are poor surgical candidates due to other concomitant illnesses.

As mentioned above, another conventional treatment is percutaneous transluminal coronary angioplasty (PTCA) or other types of angioplasty. However, such vascular treatments are not always indicated due to the type or location of the blockage or stenosis, or due to the risk of emboli.

Thus, there is a need for an improved coronary bypass system which is less traumatic to the patient.

Summary of the Invention

Briefly stated, the methods and apparatus described and illustrated herein generally relate to direct coronary revascularization, wherein a conduit or opening is provided from the left ventricle to the coronary artery, oftentimes the left anterior descending (LAD), to provide blood flow directly therethrough. These methods and apparatus are particularly useful when a blockage partially or completely obstructs the coronary artery, in which case the bypass conduit or opening is positioned distal to the blockage. More preferably, conduits are provided to direct blood flow from the left ventricle to a coronary artery at a location distal to a blockage in the coronary artery. The conduits may be threaded to facilitate insertion into a patient's heart wall and to control the depth of insertion. Threaded and nonthreaded conduits are preferably delivered using a guidewire approach. In this approach, the guidewire is placed through a needle that is inserted into the left ventricle. After the guidewire is placed, the needle is removed. In one embodiment, a dilator is provided over the guidewire into the heart wall, and the conduit is delivered over the dilator. In another embodiment, an introducer sleeve is provided over the dilator into the heart wall, the dilator is removed, and the conduit is delivered through the introducer sleeve. A depth measuring tool is preferably used to determine the appropriate length of the conduit prior to delivery. In another embodiment, a feature can be included on the end of the introducer sleeve that engages with the arterial wall, and when pulled back, distends the artery. The conduit can then be advanced until the deployable flanges seat against the bottom of the artery.

Brief Description of the Drawings

FIGURE 1 is a schematic side view of a threaded conduit inserted into a heart wall of a patient between the left ventricle and a coronary artery according to a preferred embodiment of the present invention.

FIGURE 2 is a side view of a heart having a needle inserted through a coronary artery to the left ventricle, and a guidewire inserted therethrough.

FIGURE 2A is a side view showing a needle being inserted through a coronary artery into the left ventricle.

FIGURE 2B is a side view of a guidewire inserted through the needle of **FIGURE 2A**, with the needle being removed.

FIGURE 3 is a side view of a dilator being inserted over the guidewire of **FIGURE 2**.

FIGURE 3A is a side view of an introducer being advanced over the guidewire of **FIGURE 2B**.

FIGURE 4 is a side view of a threaded conduit being inserted over the dilator of **FIGURE 3**.

FIGURE 4A is a side view of a tool being used to insert a threaded conduit inserted over the dilator of **FIGURE 3A**.

FIGURE 5 is a side view showing the threaded conduit of **FIGURE 4** being advanced into position.

FIGURES 5A-5D are the side views of **FIGURES 2A, 2B, 3A** and **4A**, more particularly showing features included on the needle, introducer and deployment tool that aid in determining the proper deployment depth.

FIGURE 6 is a side view of a sleeve being placed for shunt insertion.

FIGURE 7A is a side view of a conduit being inserted through the sleeve of **FIGURE 6** using a stylet.

FIGURE 7B illustrates the conduit of **FIGURE 7A** having flanges.

FIGURE 8 is a side view of the stylet and sleeve of **FIGURE 7A** being removed.

FIGURES 8A-8C are side views of a delivery system for a nonthreaded conduit illustrating a bulb feature on the outer introducer sleeve that aids in holding the artery open and achieving proper placement of the device.

FIGURE 9 is a schematic side view of a two piece threaded stylet and sleeve.

FIGURE 10 is a schematic side view of a depth measuring tool.

FIGURE 11 is a cross-sectional view of an introducer sleeve having a side lumen for depth measurement.

FIGURES 12A-12D are schematic side views of the delivery of a conduit from the coronary artery to the left ventricle using a dilator and introducer.

FIGURES 13A-13B are schematic side views of threads used to hold open the coronary artery.

FIGURE 14 is a table of the pull out forces of various threaded conduits that may be used according to certain embodiments of the present invention.

FIGURE 15 is a table of pull out forces of various barbed conduits that may be used according to certain embodiments of the present invention.

FIGURE 16 is a table of push-through forces of various conduits having flanges that may be used according to certain embodiments of the present invention.

Detailed Description of the Preferred Embodiment

As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. Oxygenated blood that has returned from the lungs to the heart then flows from the heart to the aorta. Some blood in the aorta flows into the coronary arteries, and the remainder of blood in the aorta flows on to the rest of the body. The coronary arteries are the primary blood supply to the heart muscle and are thus critical to life. In some individuals, atherosclerotic plaque, aggregated platelets, and/or thrombi build up within the coronary artery, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death. The presence of coronary vasospasm, also known as "variant angina" or "Prinzmetal's angina," compounds this problem in many patients.

The principles of the present invention are not limited to left ventricular conduits, and include conduits for communicating bodily fluids from any space within a patient to another space within a patient, including any mammal. Furthermore, such fluid communication through the conduits is not limited to any particular direction of flow and can be antegrade or retrograde with respect to the normal flow of fluid. Moreover, the conduits may communicate between a bodily space and a vessel or from one vessel to another vessel (such as an artery to a vein or vice versa). Moreover, the conduits can reside in a single bodily space so as to communicate fluids from one portion of the space to another. For example, the conduits can be used to achieve a bypass within a single vessel, such as communicating blood from a proximal portion of an occluded coronary artery to a more distal portion of that same coronary artery.

In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit

communicates from the left ventricle, through the myocardium, into the pericardial space, and then into the coronary artery. However, other preferred embodiments are disclosed, including direct transmyocardial communication from a left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other non-myocardial and even non-cardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, septum, etc.

The bypass which is achieved with certain preferred embodiments and related methods is not limited to a complete bypass of bodily fluid flow, but can also include a partial bypass which advantageously supplements the normal bodily blood flow. Moreover, the occlusions which are bypassed may be of a partial or complete nature, and therefore the terminology "bypass" or "occlusion" should not be construed to be limited to a complete bypass or a complete occlusion but can include partial bypass and partial occlusion as described.

The preferred conduits and related methods disclosed herein can also provide complete passages or partial passages through bodily tissues. In this regard, the conduits can comprise stents, shunts, or the like, and therefore provide a passageway or opening for bodily fluid such as blood. Moreover, the conduits are not necessarily stented or lined with a device but can comprise mere tunnels or openings formed in the tissues of the patient.

The conduits of the present invention preferably comprise both integral or one-piece conduits as well as plural sections joined together to form a continuous conduit. The present conduits can be deployed in a variety of methods consistent with sound medical practice including vascular or surgical deliveries, including minimally invasive techniques. For example, various preferred embodiments of delivery rods and associated methods may be used. In one embodiment, the delivery rod is solid and trocar-like. It may be rigid or semi-rigid and capable of penetrating the tissues of the patient and thereby form the conduit, in whole or in part, for purposes of fluid communication. In other preferred embodiments, the delivery rods may be hollow so as to form the conduits

themselves (e.g., the conduits are preferably self-implanting or self-inserting) or have a conduit mounted thereon (e.g., the delivery rod is preferably withdrawn leaving the conduit installed). Thus, the preferred conduit device and method for installation is preferably determined by appropriate patient indications in accordance with sound medical practices.

FIGURE 1 illustrates schematically a threaded conduit according to one preferred embodiment of the present invention. The conduit 10 is preferably an elongate tubular body having a proximal end 12 and a distal end 14 and a lumen (not shown) extending therethrough. The proximal end 12 preferably tapers to the desired internal diameter (ID) of the device. The majority of the conduit 10 is threaded with threads 16 to facilitate insertion of the conduit into the heart, as described below. In one preferred embodiment, the entire body of the conduit 10 is threaded except for the proximal tip 12 of the conduit. The conduit may or may not have flange-like features 13 on its distal end that engage with the artery lumen. In addition, the conduit may or may not have a ring 15 for engaging the artery and allowing blood to pass therethrough. **FIGURE 1** illustrates the conduit 10 as implanted in a patient, wherein the conduit preferably extends between the left ventricle LV, through the myocardium MYO and into the coronary artery CA.

FIGURES 2-5 illustrate one embodiment for delivering the conduit 10 into a patient. Although these figures illustrate a pig heart, it will be appreciated that the methods described herein apply to human hearts as well. To deliver the conduit 10 into the myocardium of the heart PH, a needle 18, as shown in **FIGURE 2**, is first inserted through the heart wall into the left ventricle (also illustrated in **FIGURE 2A**). The needle 18 is preferably hollow, and is preferably inserted through an anterior wall and then a posterior wall of the coronary artery CA. After the needle is inserted, access to the left ventricle may be verified. If it is necessary to relocate the needle, the needle leaves only a very small hole upon removal.

As shown in **FIGURE 2**, after the needle is placed in the left ventricle, a guidewire 20 is inserted into the lumen in the needle. The guidewire is preferably a 0.014 guidewire, which extends into the left ventricle through the needle. After placement of the guidewire the needle is removed, as illustrated in **FIGURE 2B**.

As shown in **FIGURES 3** and **3A**, a dilator or introducer 22 is preferably inserted over the guidewire and into the heart until the dilator reaches the left ventricle. Upon reaching this position, the guidewire 20 is removed from the heart.

As shown in **FIGURES 4** and **4A**, a threaded conduit 10, such as described with respect to **FIGURE 1** above, is placed over the dilator. The non-threaded tapered tip 16 (shown in **FIGURE 1**) of the conduit is inserted into the coronary artery. The conduit 10 is then preferably pulled back to open the artery. The first few threads are then advanced by twisting the threaded conduit. The conduit 10 may be in the form of a shunt.

A tool 24 is then used to advance the conduit 10 to the proper depth, as shown in **FIGURES 5** and **4A**. More preferably, the tool 24 mates with the distal end of the conduit in order to turn the conduit. Because the conduit 10 is threaded, the tool 24 can easily adjust the conduit to a desired depth. After the conduit 10 reaches the desired depth, the tool and the dilator are removed, leaving the conduit 10 in place.

In **FIGURES 5A-5D**, features are shown on the components of the delivery system illustrated in **FIGURES 2A, 2B, 3A** and **4A** to help determine the proper depth to insert the device. As shown in **FIGURE 5A**, depth markers 19 on the needle 18 can be used to determine the thickness of the myocardium, and ensure that the device used will reach the left ventricle. As shown in **FIGURES 5C** and **5D**, a bleed hole 23 in the dilator/introducer 22 can be used to determine the location of the lumen of the artery, and a depth marker 25 on the dilator/introducer, coupled with a window 27 in the deployment tool 24, can be used to determine when the threaded device 10 has been inserted to the proper depth.

FIGURES 6-8 illustrate another embodiment for delivering a conduit into a patient's heart, where the conduit need not be threaded. As described and shown with respect to **FIGURES 2** and **3** above, a dilator is preferably placed into the heart through the coronary artery using a needle and a guidewire. As shown in **FIGURE 6**, a sleeve 26 is placed over the dilator and inserted into the patient's heart. The dilator is then removed.

As shown in **FIGURE 7A**, a conduit 10 is inserted into the sleeve 26. The conduit may be in the form of a shunt, as illustrated in **FIGURE 7A**. The conduit, as shown in **FIGURE 7B**, may have flanges 28 on its distal end 14 which will assist in

anchoring the conduit 10 to the artery. The conduit 10 is placed in the sleeve 26 by collapsing the flanges 28 into the sleeve. The conduit is advanced using a stepped stylet 30, as shown in **FIGURE 8**, to the proper depth. This depth may be determined using an external depth measuring gauge. Holding the stylet 30 stationary, the sleeve is removed, releasing the flanges 28, preferably in the artery CA. Then the stylet is removed, leaving the conduit 10 in place.

In **FIGURES 8A-8C**, another embodiment for inserting a non-threaded conduit is shown, wherein a bulbous feature is included on a sleeve for holding the artery open.

In this embodiment, the dilator 22, conduit 10, and sleeve 26 are assembled as shown, and inserted through the coronary artery and into the myocardium until the bulbous feature 29 is inside the lumen of the artery. The assembly is then pulled back, so that the bulbous feature 29 distends the artery. The stepped dilator 22 is then pushed into the left ventricle, advancing the conduit 10 while the sleeve 26 is held in place. The flanges 28 then deploy outside the sleeve, but inside the artery. The conduit can be advanced until the flanges bottom out on the bottom wall of the artery, then the sleeve 26 and dilator 22 can be removed. Several configurations of bulbous features can be incorporated, including a short threaded section, a balloon, or any deployable features that extend past the outer diameter (OD) of the sleeve thereby anchoring the sleeve in the lumen of the artery. It is also understood that the dilator, conduit, and sleeve can be inserted as an assembly, or individually in which case the conduit is backloaded into the sleeve after the sleeve has been placed.

It will be appreciated that various conduit configurations can be used in accordance with the embodiments of the present invention. For instance, threaded conduits, conduits with barbs and conduits with flanges may all be used. **FIGURE 14** shows a table of the pull out forces of various threaded conduits that may be used. **FIGURE 15** shows a table of the pull out forces of various barbed conduits that may be used. **FIGURE 16** shows a table of the push-through forces of various conduits having flanges that may be used.

FIGURE 9 illustrates a two piece threaded stylet and sleeve for delivery of a conduit. The stylet 54 is preferably threaded only on its distal tip 56 which is to be inserted into the myocardium MYO to the left ventricle. The sleeve 58 is preferably

threaded over its entire body. The stylet 54 and the sleeve 58 are preferably threaded simultaneously into the myocardium. The stylet is then removed, and a conduit (not shown) for providing blood flow between the left ventricle and coronary artery is inserted through the sleeve while the threads on the sleeve hold the artery open. After insertion of the conduit the sleeve is removed. Alternatively, the threaded sleeve can function as the conduit itself.

In another embodiment, not shown, a method is provided for insertion of a curved conduit. This embodiment is useful where it is desired to provide a curved conduit between the left ventricle and coronary artery. A curved stylet is preferably inserted into the heart wall from the coronary artery to the left ventricle. A nonthreaded conduit is advanced over the curved stylet using a threaded flexible tool placed over the conduit. The threaded flexible tool is preferably attached to the conduit in order to advance the conduit over the stylet. The conduit is inserted by turning the tool until the conduit is in its desired location. In this embodiment, the conduit can be rigid or flexible.

FIGURE 10 illustrates a depth measuring tool 72 for measuring the depth of the coronary artery and/or myocardium. In one embodiment, the tool 72 has a proximal end 74 with an access port 78 in fluid communication with an opening 80 on the distal end 76. Also on the distal end are markers 82 used to measure the depth of insertion of the access port 78. The proximal end is preferably tapered, and is inserted into the myocardium to the left ventricle. When the access port reaches the left ventricle, blood flows through the port and out the opening. At this point the depth of the myocardium can be determined with the markers 82. A bypass conduit 84 can then be inserted over the tool, the conduit having a length determined based on the depth d of the myocardium measured by the tool 72.

In another embodiment shown in **FIGURE 11**, a depth measuring tool may be implemented within an introducer sleeve 26 such as described above. In this embodiment, the sleeve 26 has a main lumen 32 for introduction of the conduit as described above, and also has a secondary lumen 34 in fluid communication with an access port 36 for measuring the depth of insertion of the introducer sleeve. For instance, when the sleeve 26 is inserted through the heart wall toward the left ventricle, when the sleeve reaches the left ventricle blood flows through the access port and out an opening 38 on the opposite end. Once this location is reached, markers provided on the outside

of the sleeve, as described with respect to **FIGURE 10**, are used to determine the desired size of the conduit to be inserted through the lumen 32. It will be appreciated that the depth measuring tools described above may be calibrated so that the access port is located in the coronary artery to indicate positioning therein.

FIGURES 12A-12D illustrate the delivery of a conduit 86 using a dilator and an introducer according to another embodiment of the present invention. As shown in **FIGURE 12A**, a template 88 is placed on the outside of the heart for positioning and a needle 90 is inserted therethrough into the coronary artery, through the myocardium and into the left ventricle. The needle 90 is hollow, and a guidewire 92 is inserted through the needle to the left ventricle, as shown in **FIGURE 12B**. A dilator 94 is loaded onto the guidewire into the myocardium, as shown in **FIGURE 12C**. An introducer sheath 96 is advanced over the dilator until the end of the sheath is in the artery lumen. The artery is opened, and the dilator 94 is removed. As shown in **FIGURE 12D**, the conduit 86 is advanced through the introducer sheath, with a pusher or stylet 98 to advance the conduit into the myocardium.

In another embodiment, shown in **FIGURES 13A** and **13B**, coarse threads are used on a device or a tool to hold open the artery. As shown in **FIGURE 13A**, threads 100 which are exemplarily shown are used to penetrate the outer wall of the coronary artery. These threads may be independent as shown, or may be part of a conduit or delivery tool or other member. After the threads penetrate the wall, the threads or the device on which they are attached are pulled back to open the artery. Threading continues as shown in **FIGURE 13B** through the inner wall of the coronary artery.

The embodiments illustrated and described above are provided merely as examples of certain preferred embodiments of the present invention. Other changes and modifications can be made from the embodiments presented herein by those skilled in the art without departure from the spirit and scope of the invention, as defined by the appended claims.

WHAT IS CLAIMED IS:

1. A conduit for providing a passageway of blood between a chamber of the heart and an adjacent blood vessel through a heart wall, comprising:

an elongate body having a proximal end and a distal end and a lumen extending therethrough; and

an engagement mechanism on a distal end of the elongate body configured to engage the blood vessel.

2. The conduit of claim 1, wherein the engagement mechanism includes at least one flange-like member.

3. The conduit of claim 2, wherein the engagement mechanism includes a plurality of flange-like members disposed around the distal end of the elongate body.

4. The conduit of claim 3, wherein the blood vessel is a coronary artery and the flange-like members are configured to engage a posterior wall of the coronary artery.

5. The conduit of claim 1, wherein the engagement mechanism is configured to engage an inner peripheral surface of the blood vessel.

6. The conduit of claim 5, wherein the engagement mechanism is configured as a ring allowing passage of blood therethrough.

7. The conduit of claim 1, wherein the engagement mechanism engages a wall of the blood vessel adjacent the heart wall.

8. The conduit of claim 7, wherein the blood vessel is a coronary artery and the wall of the blood vessel is a posterior wall.

9. A method of delivering a conduit into a heart wall between a heart chamber and an adjacent blood vessel, comprising:

inserting a hollow needle through an anterior and a posterior wall of the blood vessel through the heart wall and into the heart chamber;

inserting a guidewire through the hollow needle into the heart chamber;

removing the hollow needle;

inserting a dilator over the guidewire into the heart wall;

removing the guidewire; and

placing a conduit over the dilator into the heart wall.

10. The method of claim 9, further comprising measuring a thickness of the heart wall prior to placing the conduit.

11. The method of claim 9, further comprising determining if the needle has entered the heart chamber.

12. The method of claim 11, wherein the determining includes providing an access port near a proximal end of the needle and an opening in flow communication with the access port near a distal end of the needle such that blood enters the access port and exits the opening when the access port on the needle has been inserted into the heart chamber.

13. The method of claim 9, wherein placing the conduit includes screwing the conduit into the heart wall.

14. A device for measuring a depth of insertion into a heart, comprising:

an elongate tubular body having a proximal end and a distal end and a lumen extending at least partially therethrough;

an access port near the proximal end of the elongate tubular body;

an opening near the distal end in flow communication with the access port; and

at least one depth indication mechanism visible from the outside of the tubular body for indicating depth of travel of the device,

wherein the device is configured so that when the device is inserted into the heart and reaches a blood-containing portion of the heart, blood flows through the access port and the depth indication mechanism indicates how far the distal end has traveled.

15. The device of Claim 14, wherein the device is configured to permit advancement of a conduit to be placed between a heart chamber and a coronary artery.

16. The device of Claim 14, wherein the lumen extending at least partially through the elongate tubular body is a side lumen.

17. The device of Claim 14, further comprising a second lumen located adjacent the lumen extending at least partially through the elongate body, the second lumen being configured to receive a conduit to be placed between a heart chamber and a coronary artery.

18. A method of providing direct blood flow between a heart chamber and a coronary vessel, the method comprising:

placing a guide device through an anterior wall and a posterior wall of the coronary vessel and through a heart wall between the heart chamber and the coronary vessel;

forming a passageway in the heart wall at a location defined by the guide device; and

placing a conduit within the passageway.

19. The method of claim 18, further comprising inserting a hollow needle through the anterior wall and posterior wall of the coronary vessel and the heart wall prior to placing the guide device.

20. The method of claim 19, wherein the guide device is a guidewire and placing the guide device includes inserting the guidewire through the hollow needle until an end of the guidewire rests in the heart chamber.

21. The method of claim 20, further comprising removing the hollow needle after inserting the guidewire through the hollow needle.

22. The method of claim 19, further comprising measuring a depth of insertion of the hollow needle.

23. The method of claim 22, wherein measuring the depth of insertion includes viewing a depth indication mechanism on the exterior of the needle.

24. The method of claim 23, wherein the depth indication mechanism includes at least one marking.

25. The method of claim 18, further comprising placing the guide device at an angle relative to the posterior wall of the coronary vessel.

26. The method of claim 25, wherein placing the guide device at the angle includes inserting a hollow needle at the angle through the anterior wall and the posterior wall of the coronary vessel and the heart wall prior to placing the guide device.

27. The method of claim 26, further comprising inserting the hollow needle through a guide template when inserting the hollow needle at the angle.

28. The method of claim 18, wherein forming the passageway includes dilating the heart wall.

29. The method of claim 28, wherein dilating the heart wall includes inserting a dilator over the guidewire.

30. The method of claim 29, wherein the dilator is configured as a sleeve.

31. The method of claim 30, further comprising inserting a sheath over the dilator.

32. The method of claim 31, wherein placing the conduit includes inserting the conduit into the sheath.

33. The method of claim 18, further comprising delivering via the guide device a first mechanism for forming the passageway and a second mechanism for placing the conduit within the passageway.

34. The method of claim 33, wherein the first and second mechanisms are delivered via the guide device to the heart simultaneously.

35. The method of claim 34, wherein the first mechanism is delivered via the guide device to the heart and, after the first mechanism is removed from the heart via the guide device, the second mechanism is delivered via the guide device to the heart.

36. The method of claim 18, further comprising measuring a distance from the anterior wall of the coronary vessel to the left ventricle prior to placing the guide device.

37. The method of claim 18, wherein the guide device is a guidewire.

38. The method of claim 18, further comprising inserting a sheath in the passageway.

39. The method of claim 38, wherein placing the conduit includes inserting the conduit into the sheath.

40. A device for measuring the depth of penetration from an anterior wall of a coronary vessel to a heart chamber, comprising:

a hollow member defining a lumen and having a distal end and a proximal end, the hollow member being configured to be inserted into the coronary artery and the heart wall;

a depth indication mechanism on the hollow member; and

a portion of the member in flow communication with the lumen of the member so that blood from the heart chamber entering the lumen can be observed.

41. The device of claim 40, wherein the depth indication mechanism includes at least one marking on a surface of the hollow member.

42. The device of claim 41, wherein the depth indication mechanism includes a plurality of graduated markings.

43. The device of claim 40, wherein the portion includes an opening.

44. The device of claim 40, wherein the hollow member is a needle.

45. The device of claim 40, further comprising an access port disposed near the proximal end of the needle, said access port being in flow communication with the lumen.

46. The device of claim 40, wherein the portion is near a distal end of the needle.

47. A conduit for providing a passageway of blood between a chamber of the heart and an adjacent blood vessel through a heart wall, comprising:

an elongate body having a proximal end and a distal end and a lumen extending therethrough; and

threads extending around the outside of the elongate body to secure the body to the heart wall.

48. A device for insertion into the heart wall of a patient, comprising an elongate body having threads to be screwed into the heart wall.

49. A method for inserting a conduit into a heart wall between a heart chamber and the coronary artery, comprising:

screwing a stylet having a threaded tip and a nonthreaded body portion into the heart wall;

screwing an outer sleeve having a threaded exterior over the nonthreaded body portion of the stylet;

removing the stylet; and

inserting the conduit into the heart wall through the outer sleeve.

50. A method for advancing a device into the heart wall of a patient through a coronary artery, comprising:

screwing a threaded device into the coronary artery to open the artery;

pulling back on the artery; and

screwing the threaded device into the heart wall.

51. A method of delivering a conduit into a heart wall between a heart chamber and an adjacent blood vessel, comprising:

inserting a hollow needle into the heart wall through the blood vessel into the heart chamber;

inserting a guidewire through the hollow needle into the heart chamber;

removing the hollow needle;

inserting a dilator over the guidewire into the heart wall;

removing the guidewire; and

screwing a threaded conduit over the dilator into the heart wall.

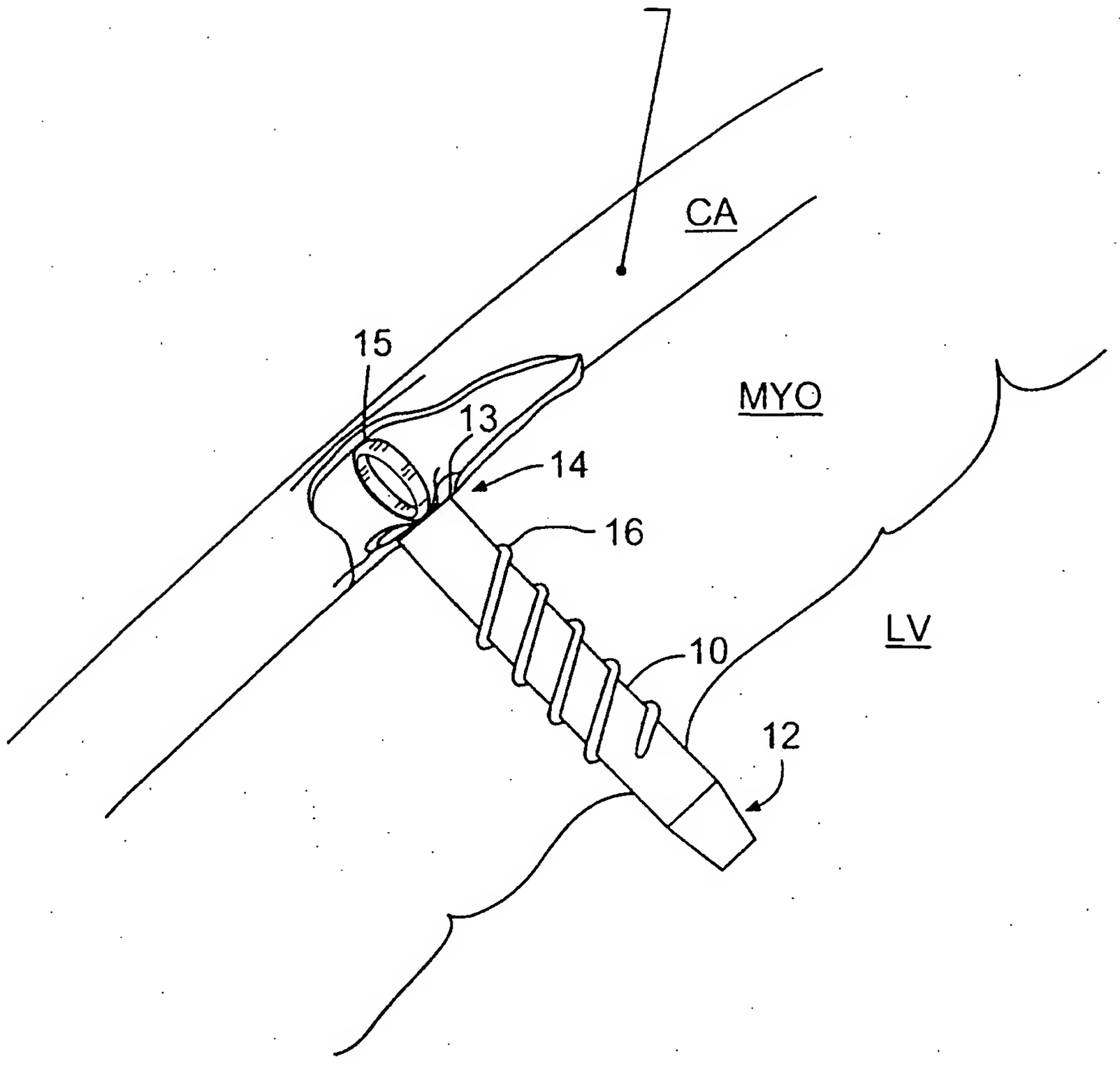

FIG. 1

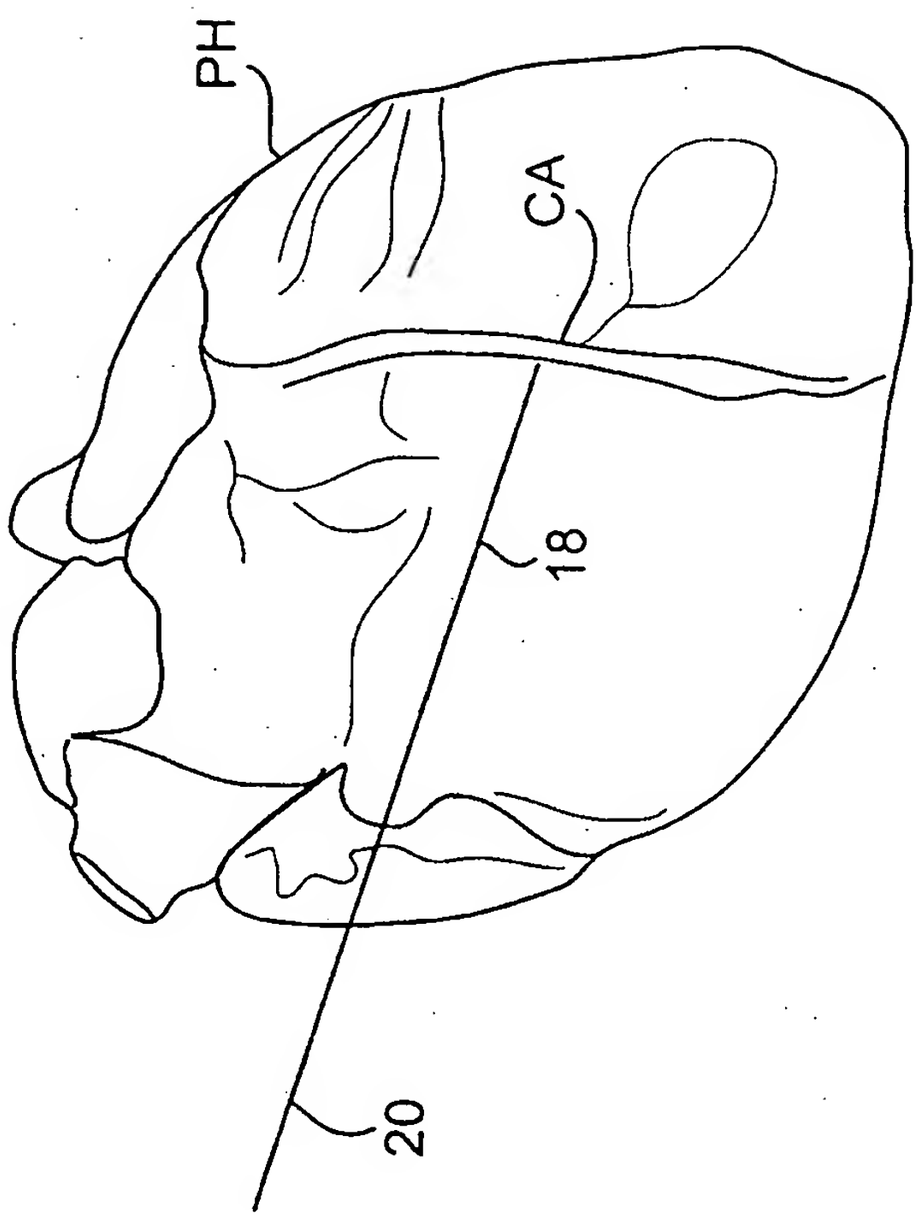

FIG. 2

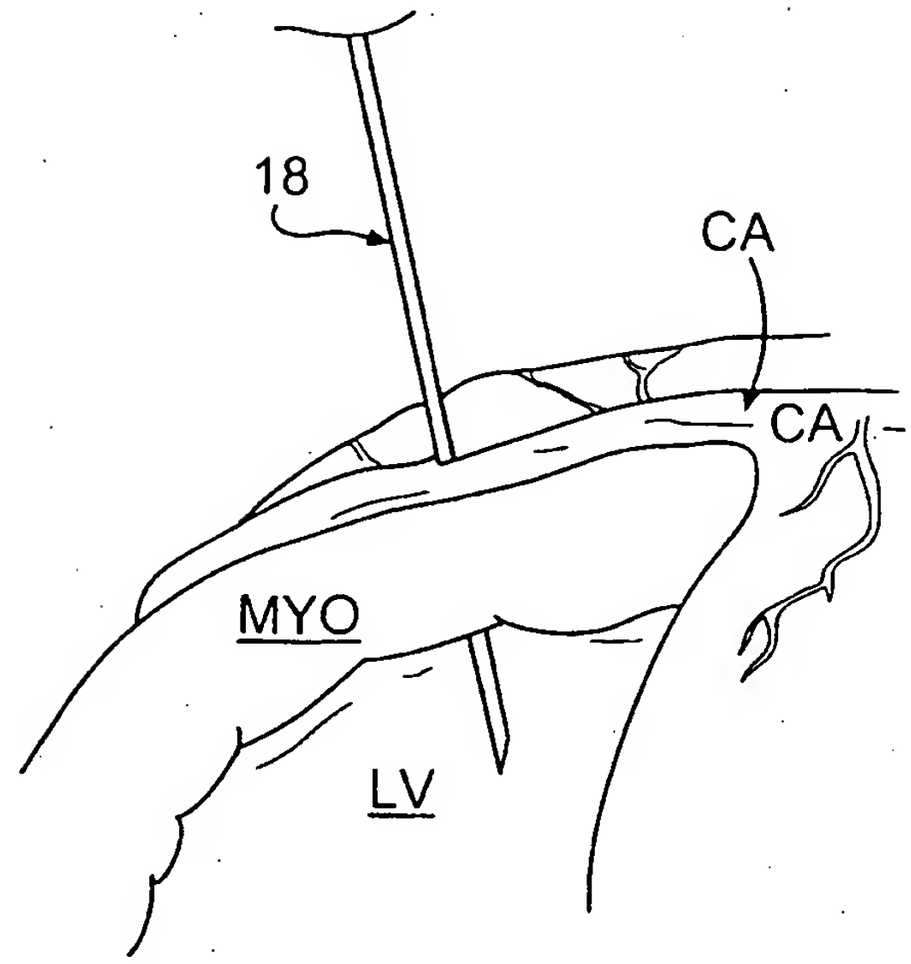

FIG. 2A

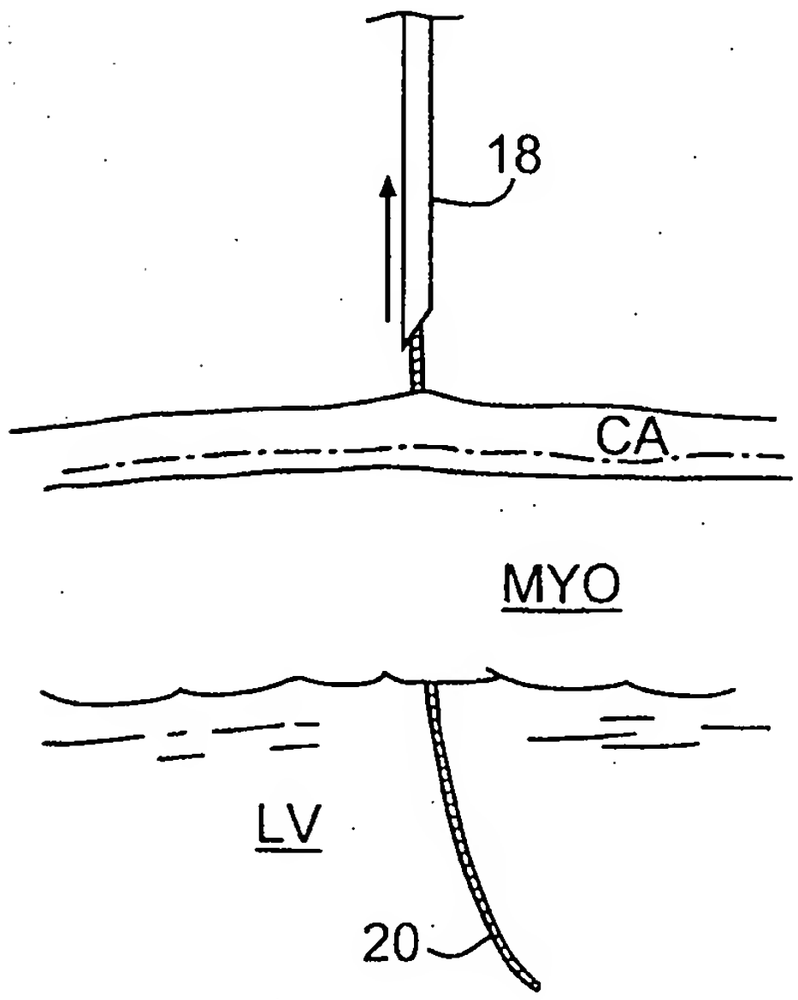

FIG. 2B

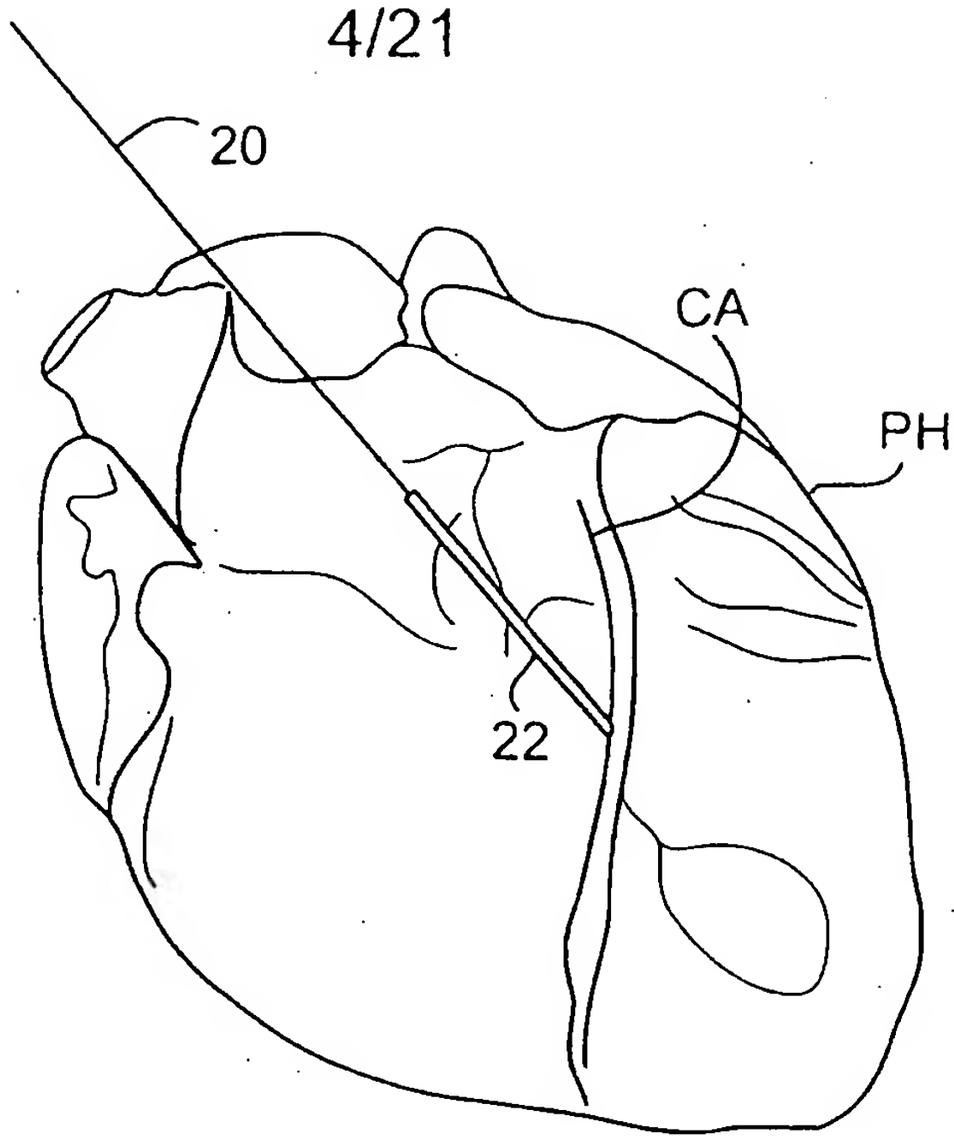

FIG. 3

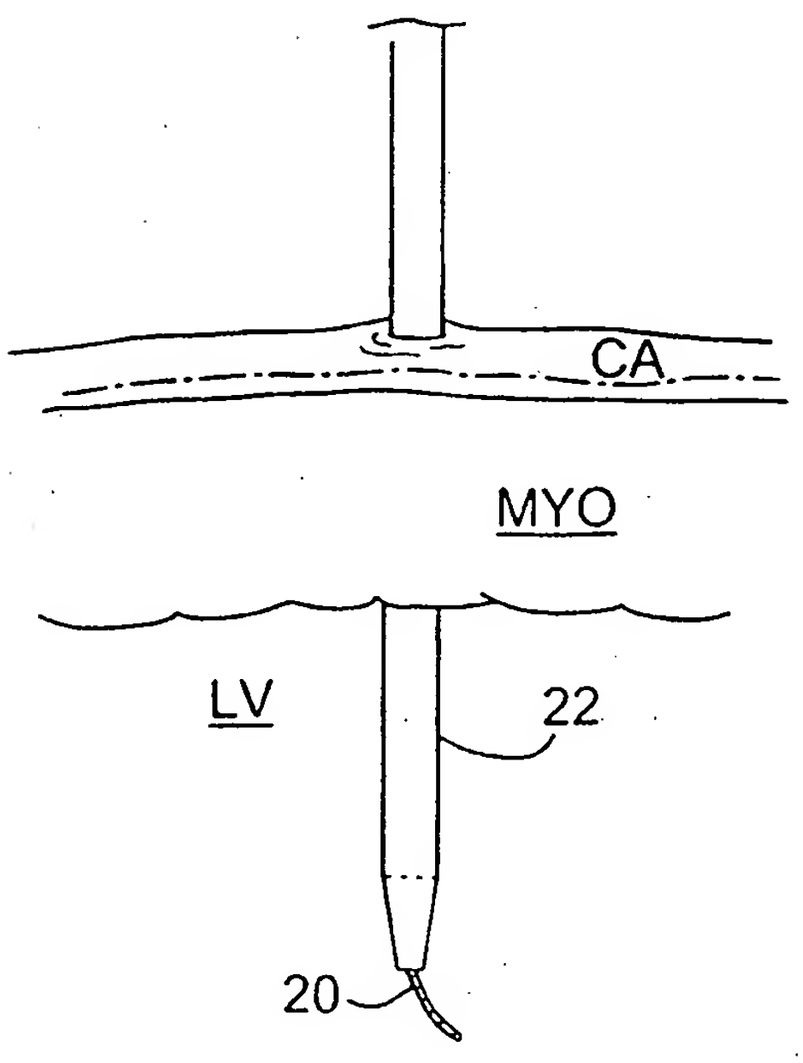

FIG. 3A

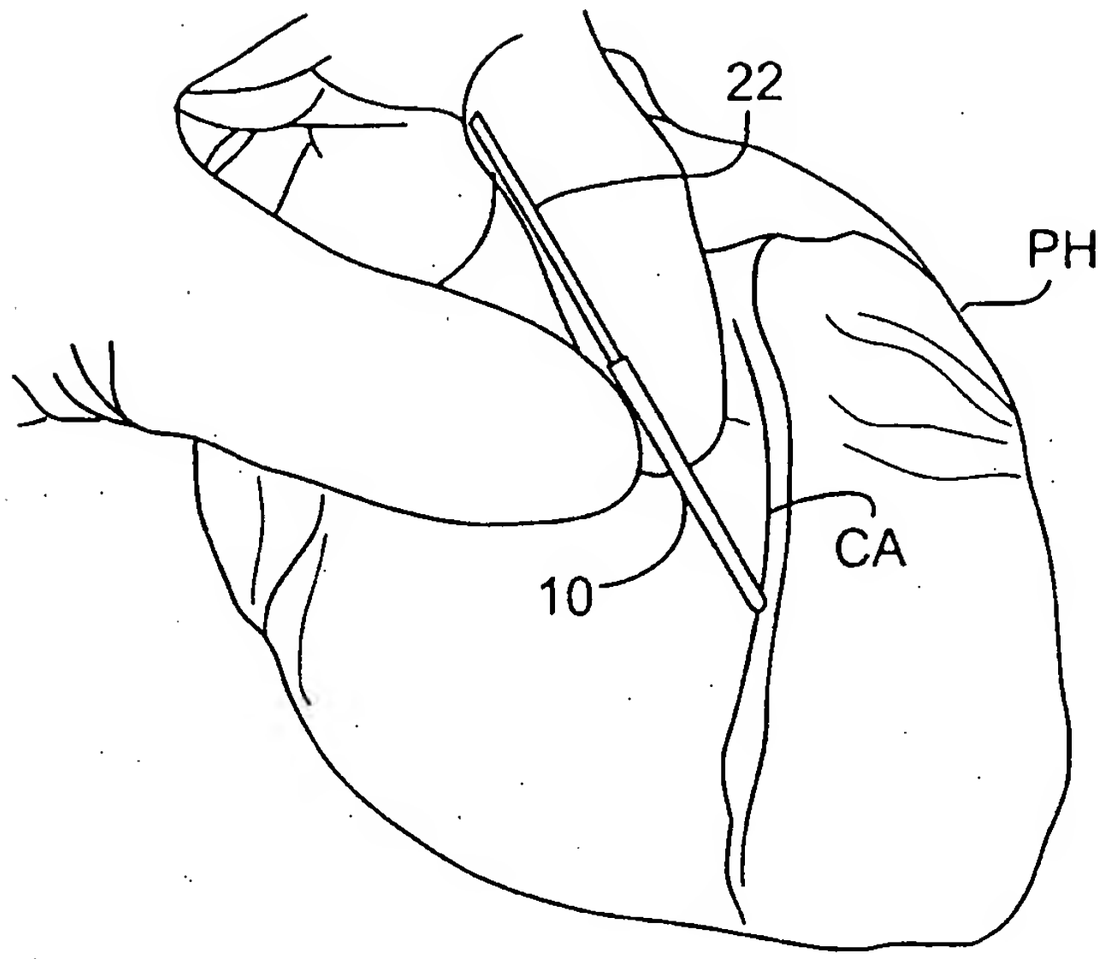

FIG. 4

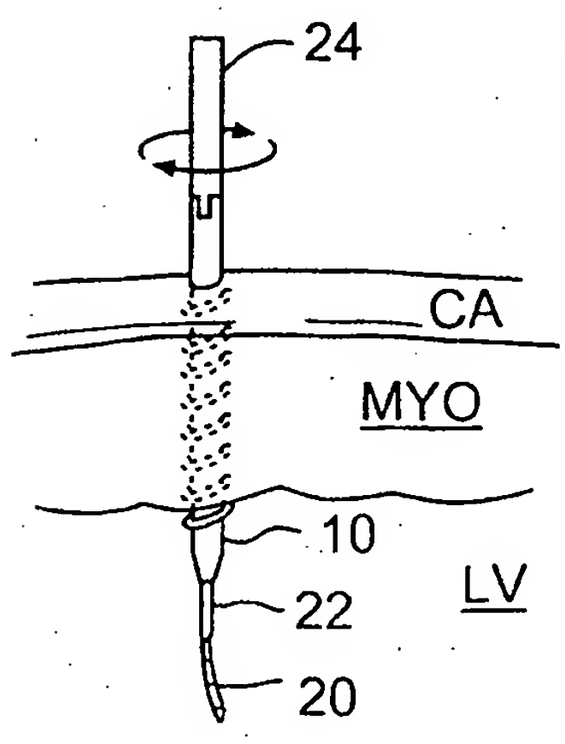

FIG. 4A

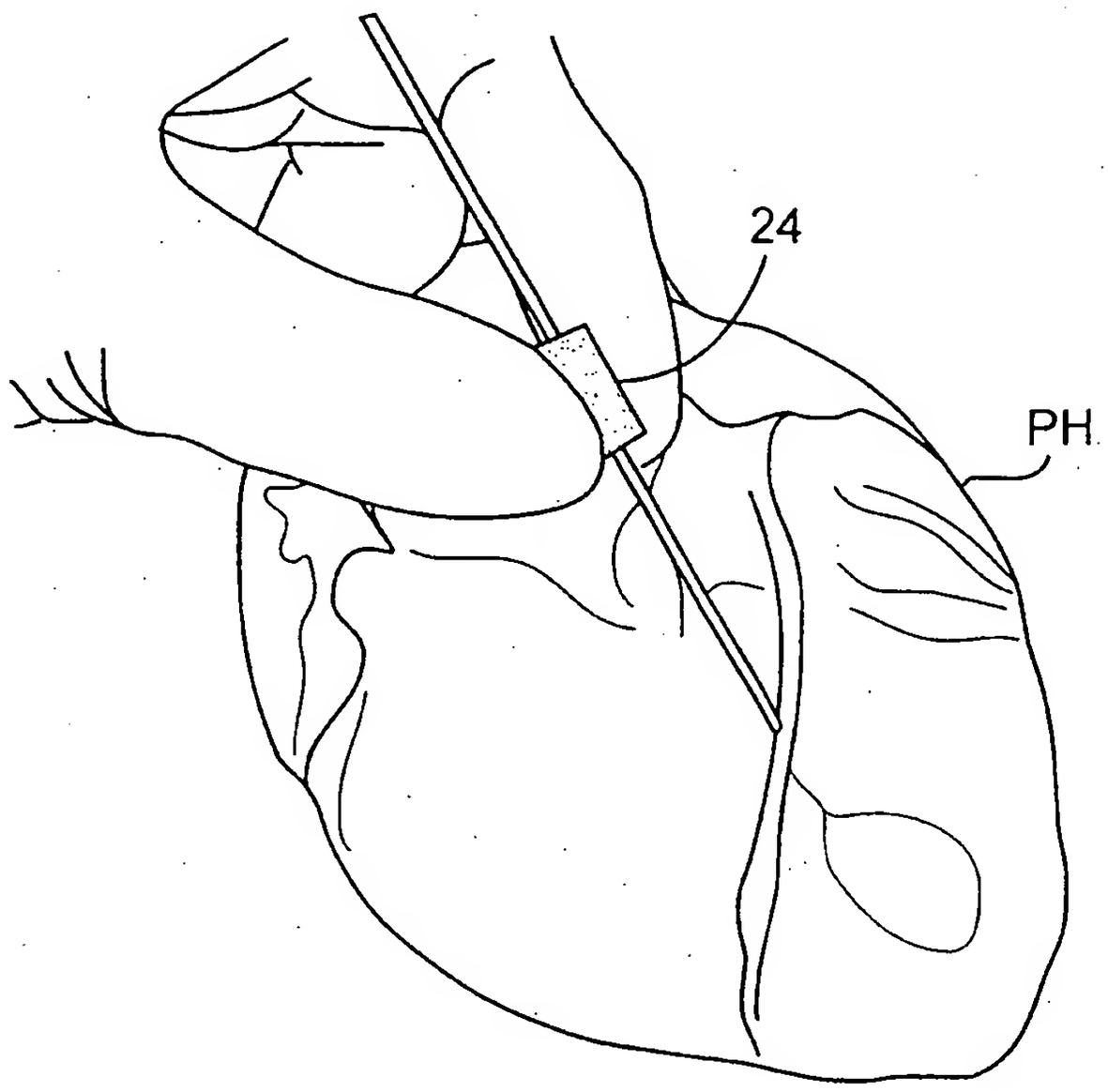

FIG. 5

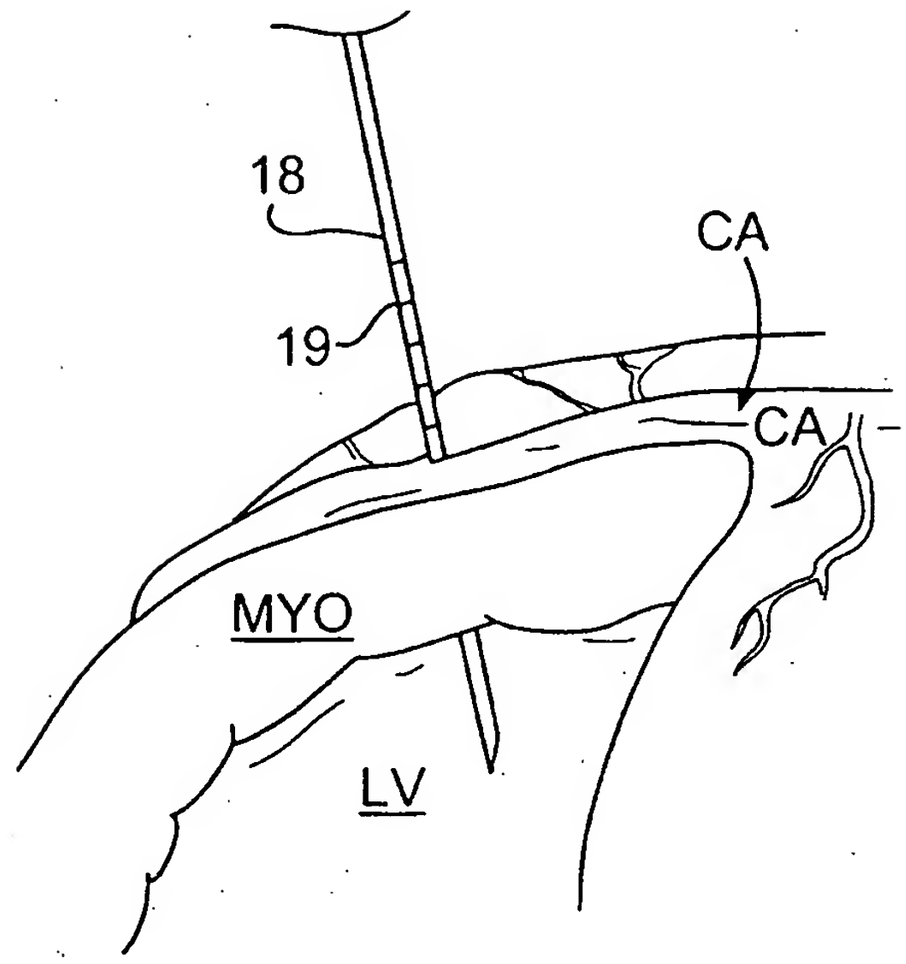

FIG. 5A

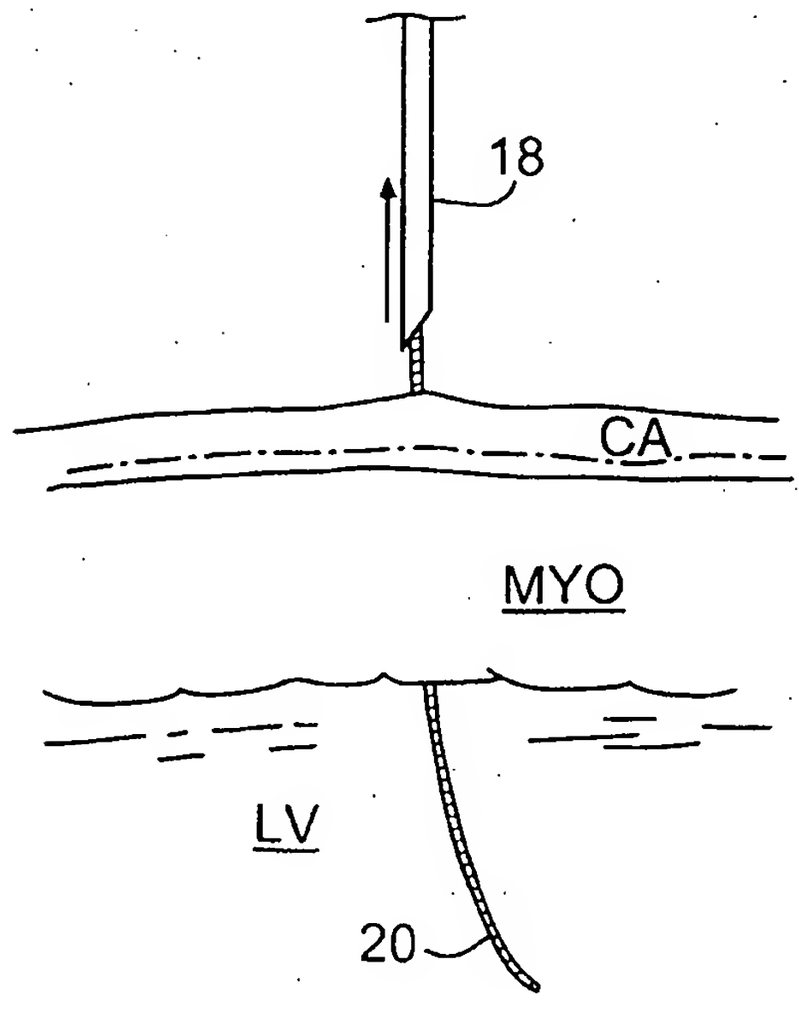

FIG. 5B

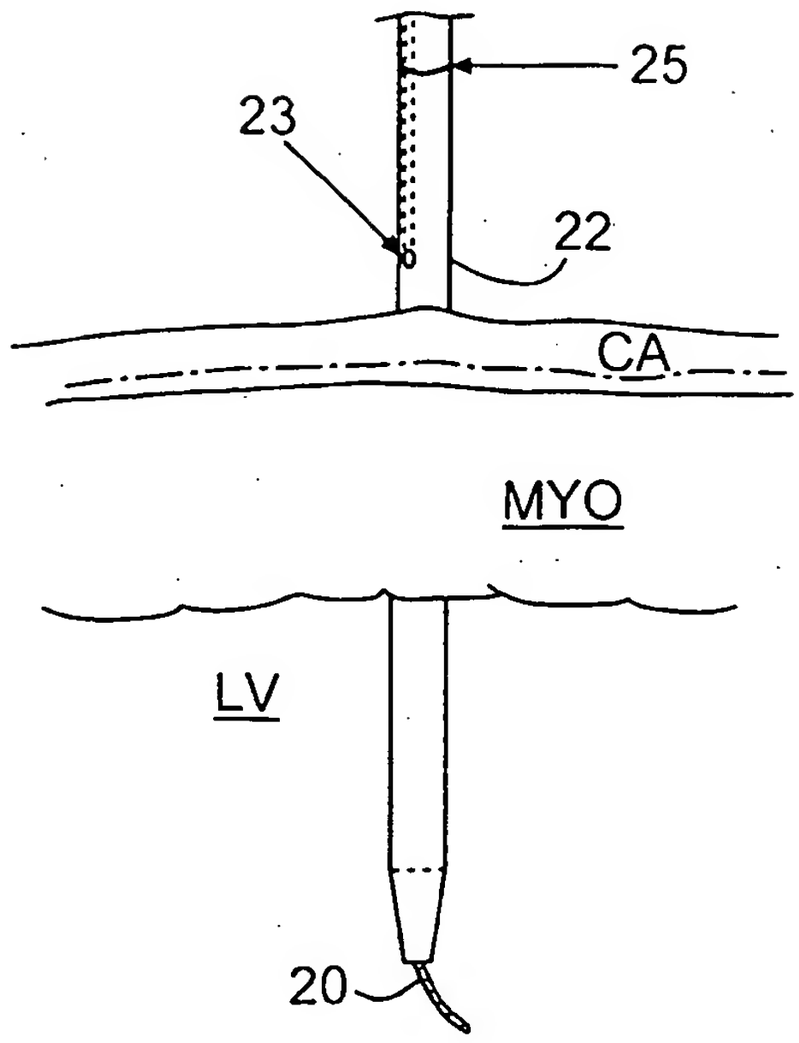

FIG. 5C

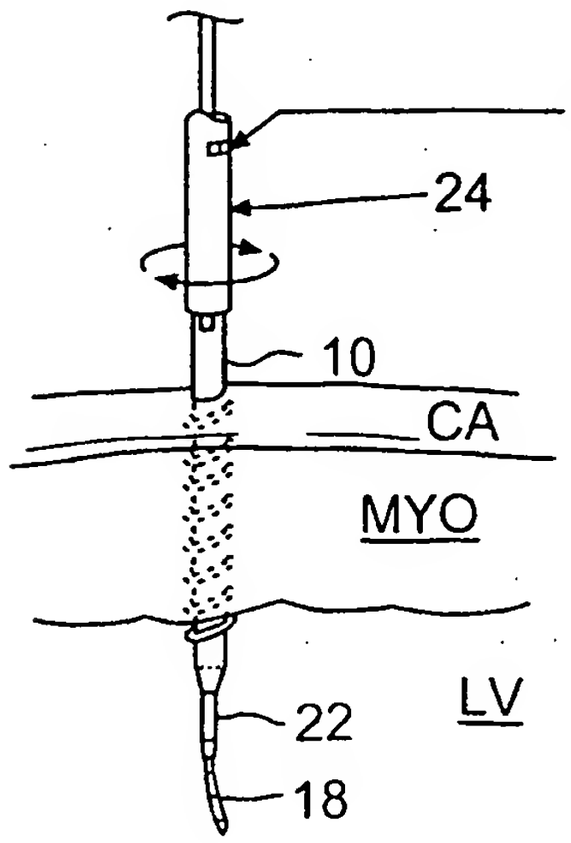

FIG. 5D

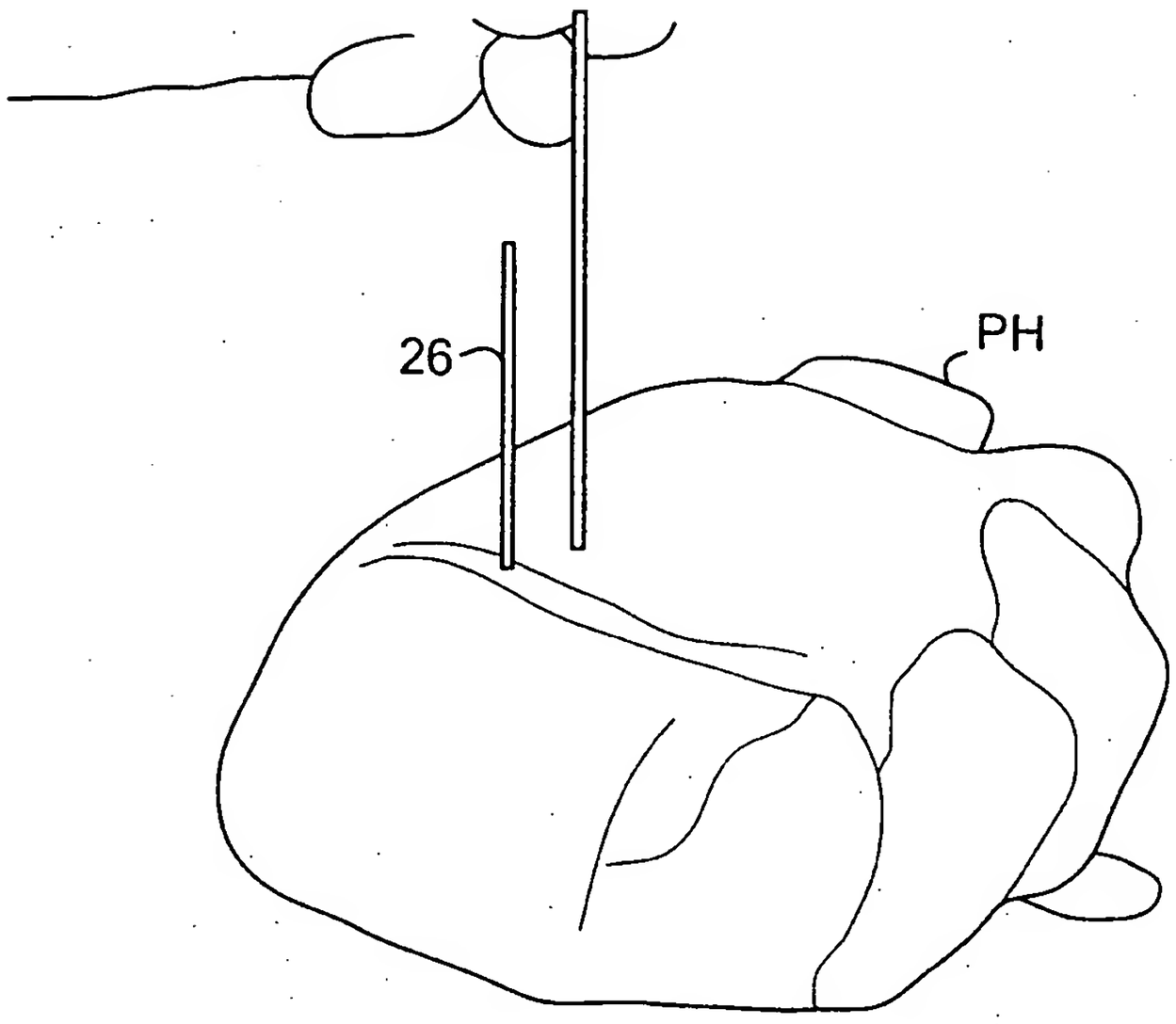

FIG. 6

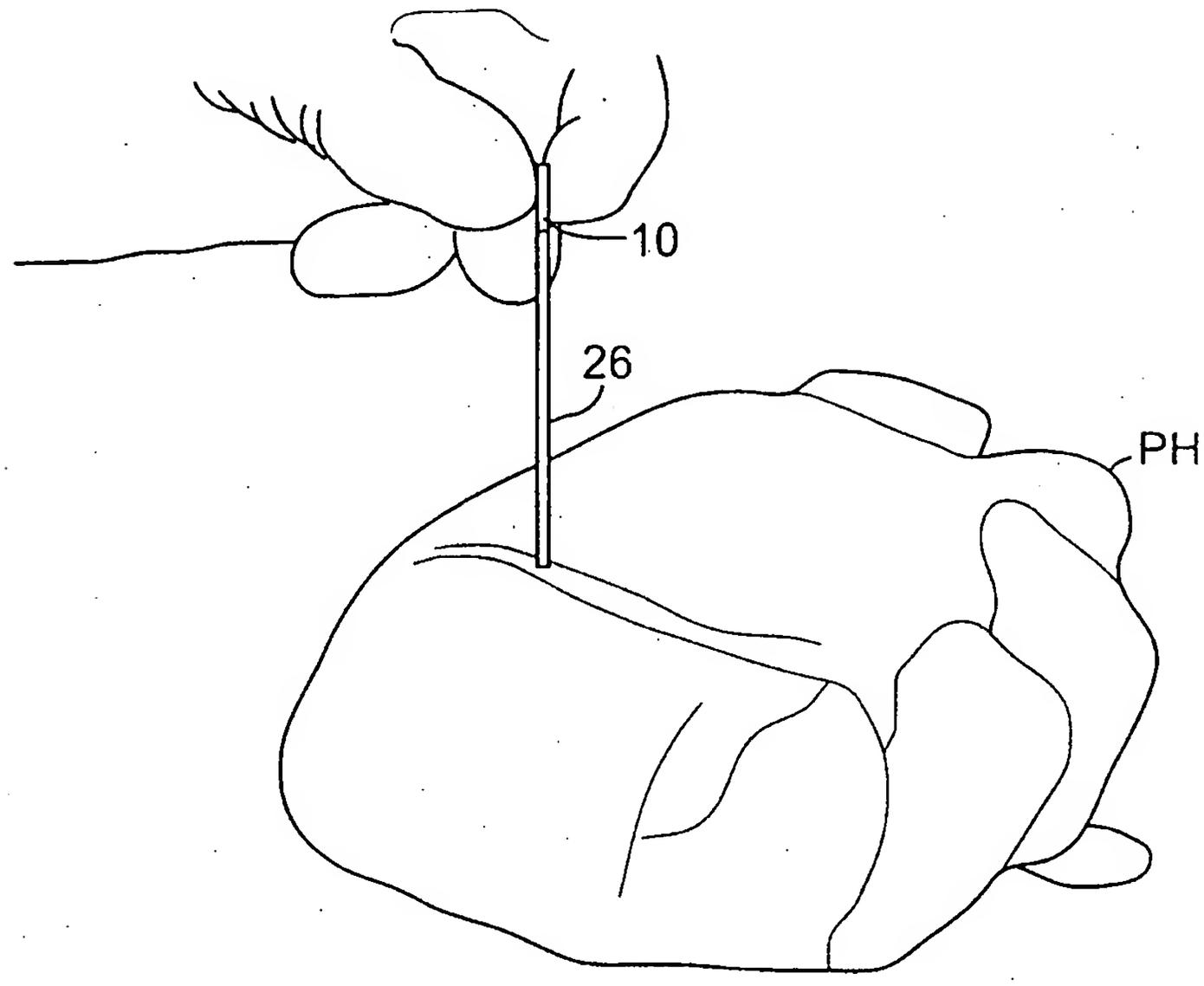

FIG. 7A

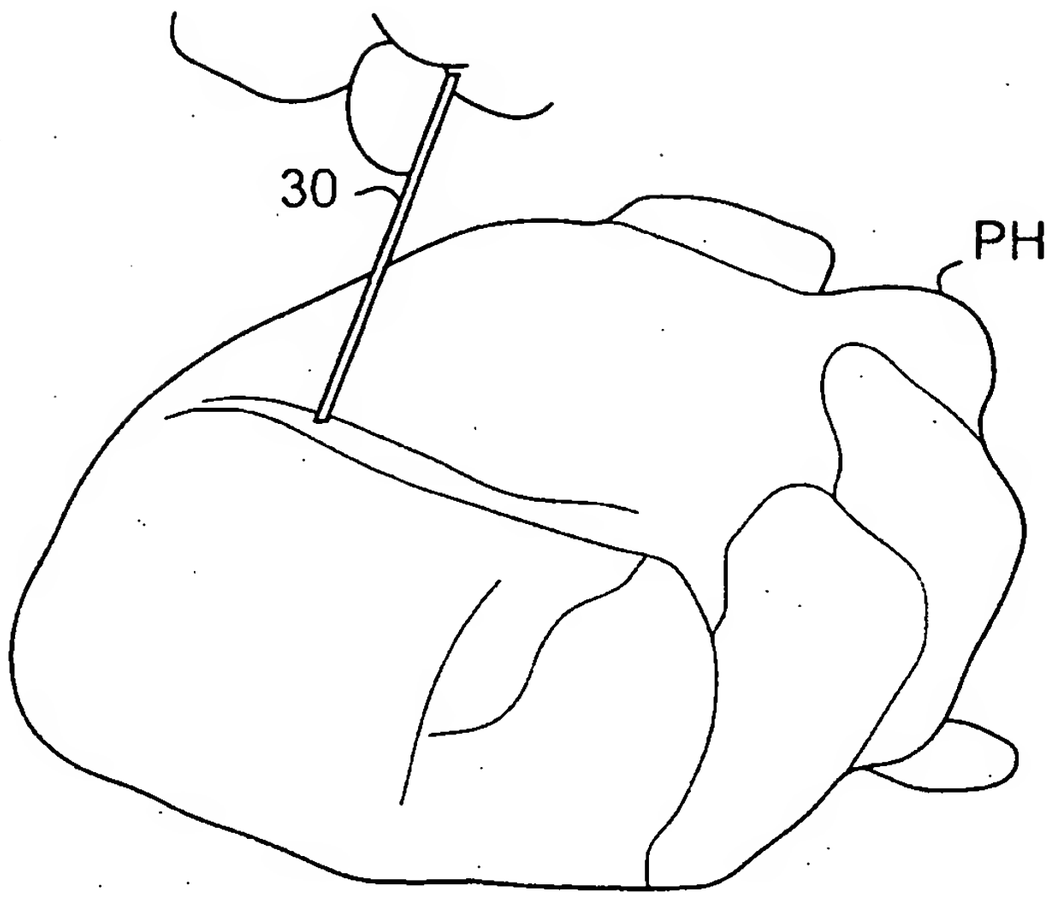

FIG. 8

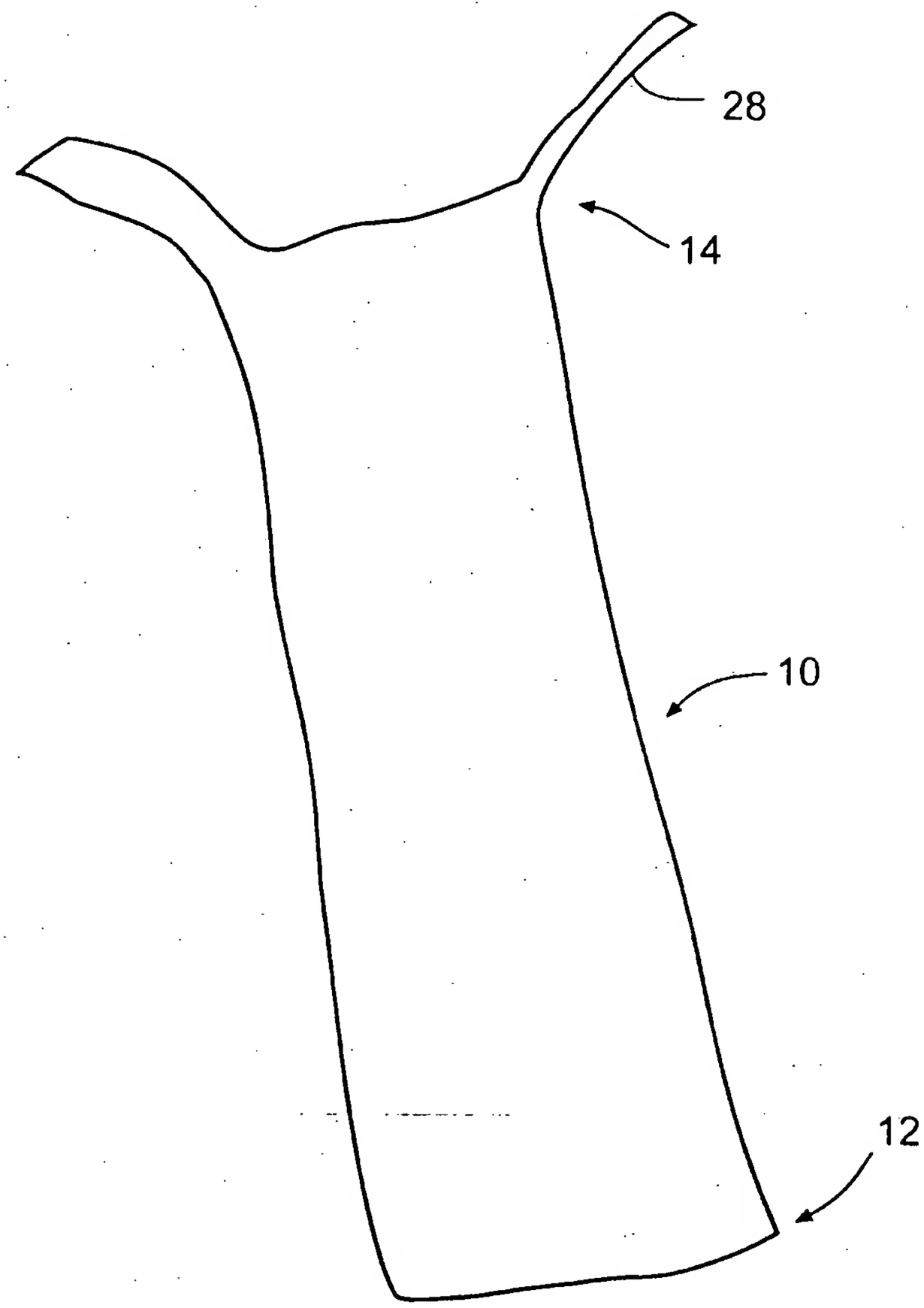

FIG. 7B

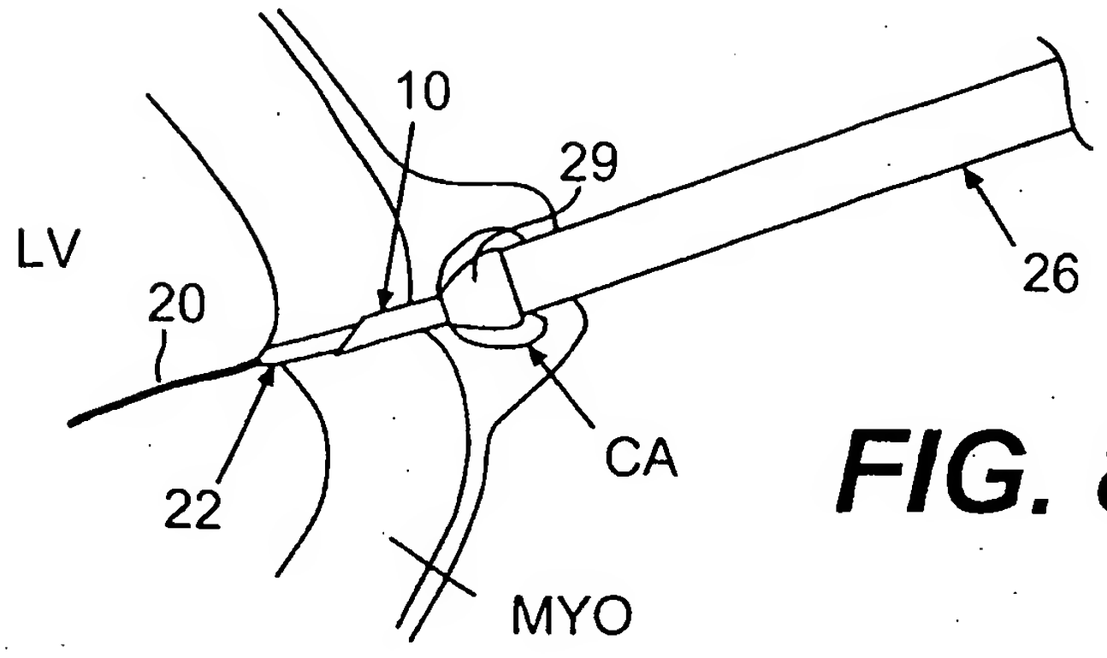

FIG. 8A

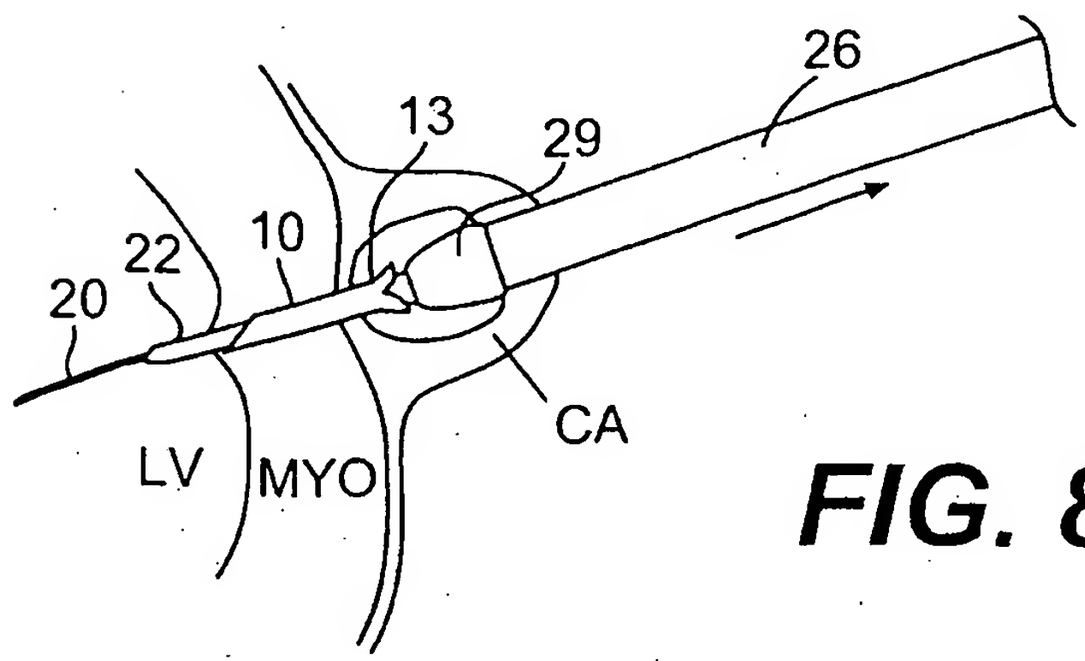

FIG. 8B

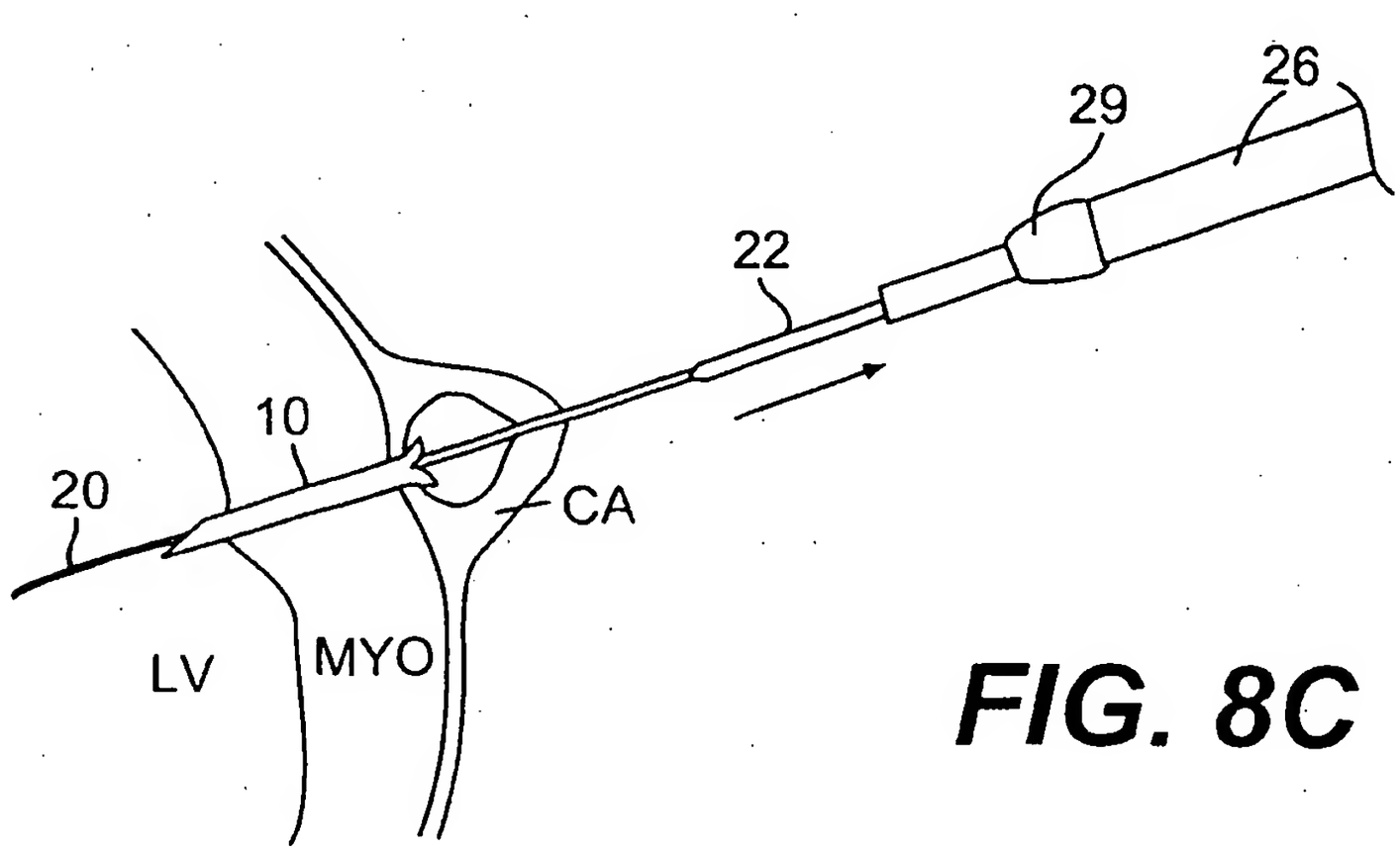

FIG. 8C

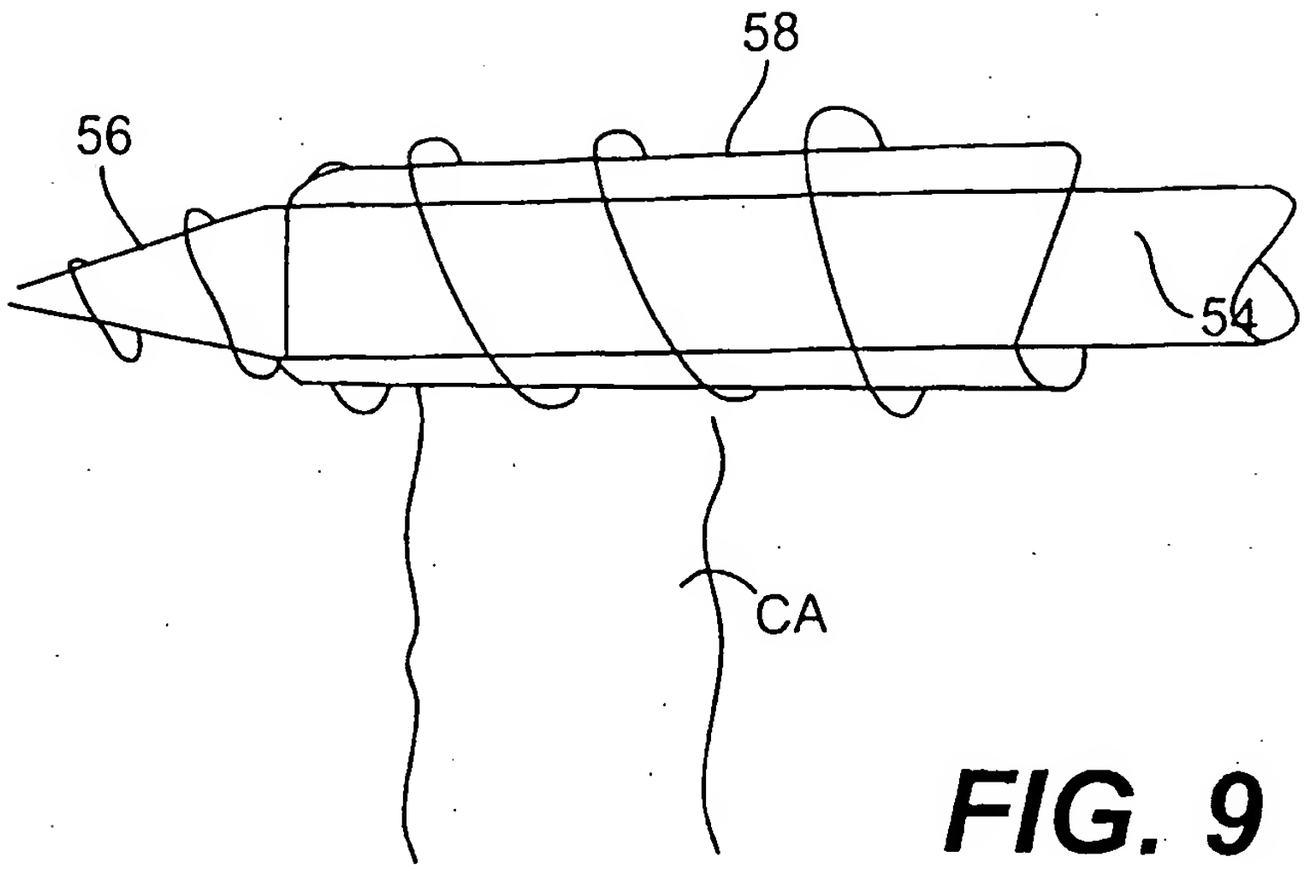

FIG. 9

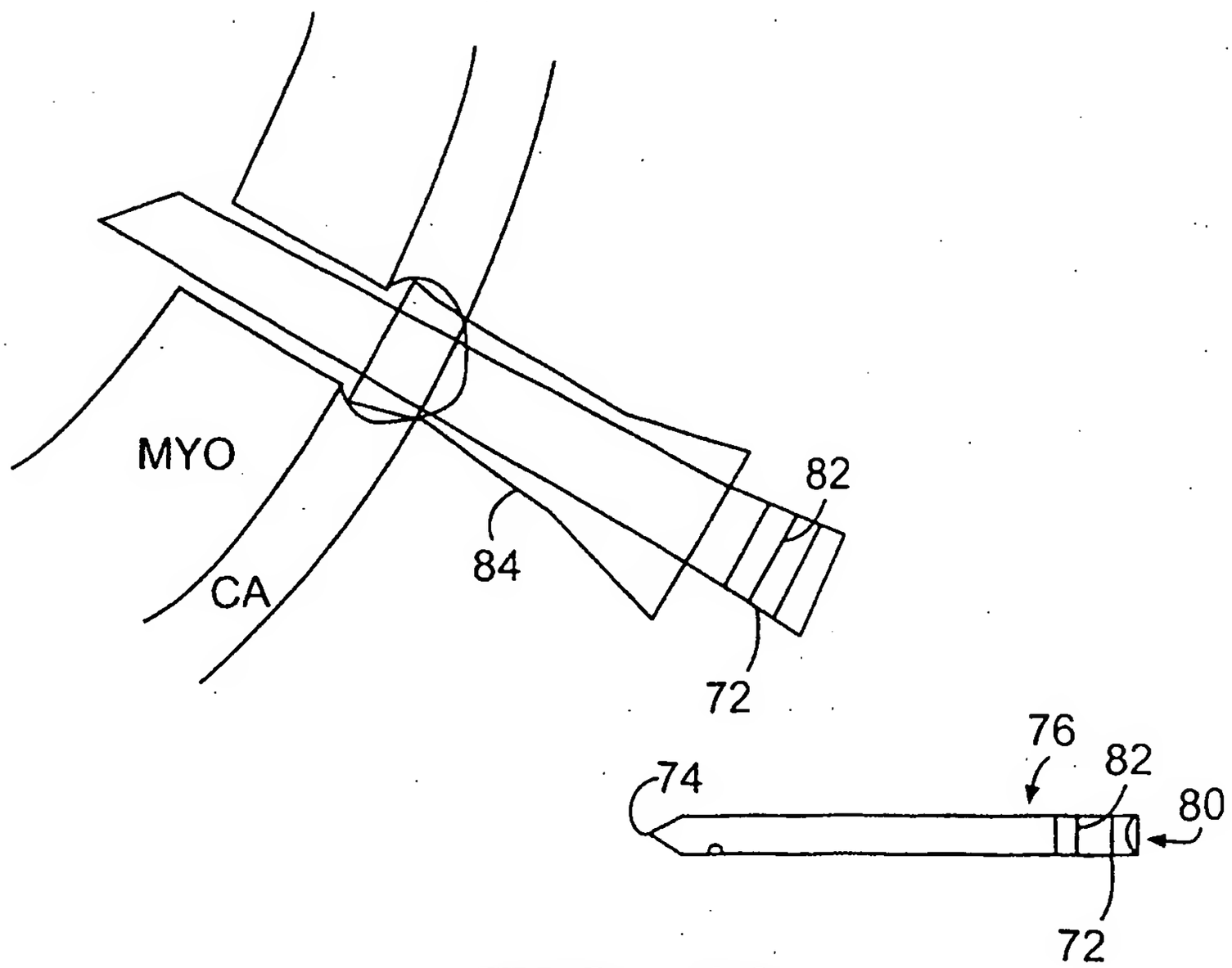

FIG. 10

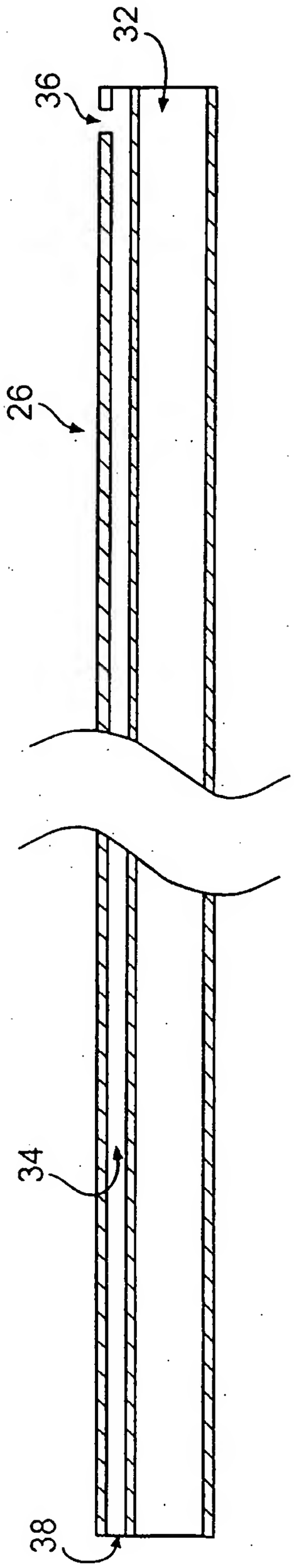

FIG. 11

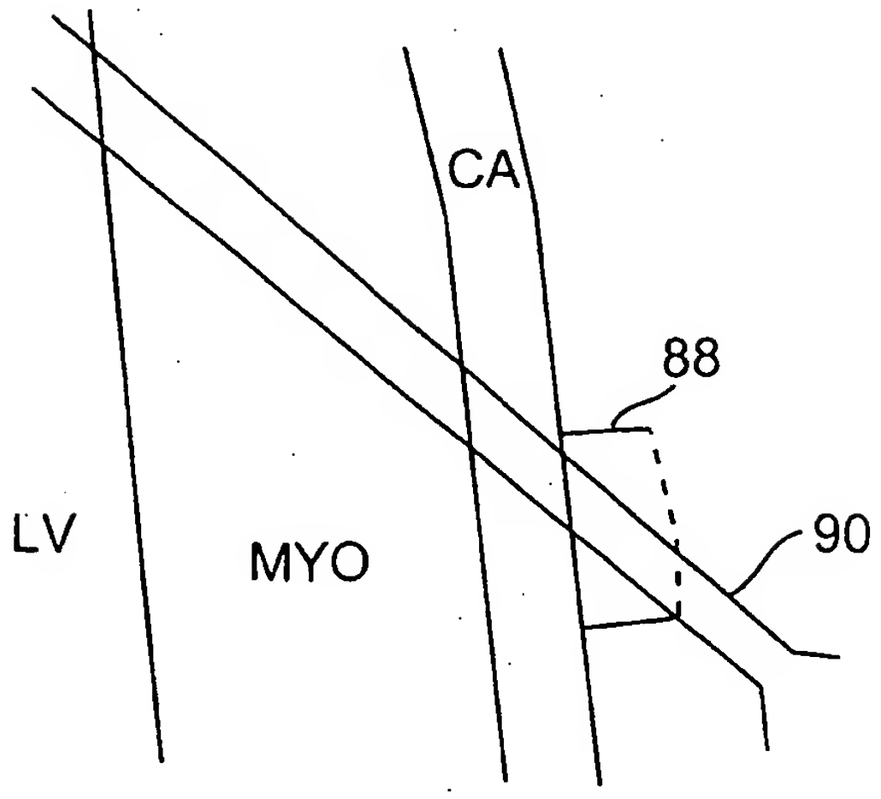

FIG. 12A

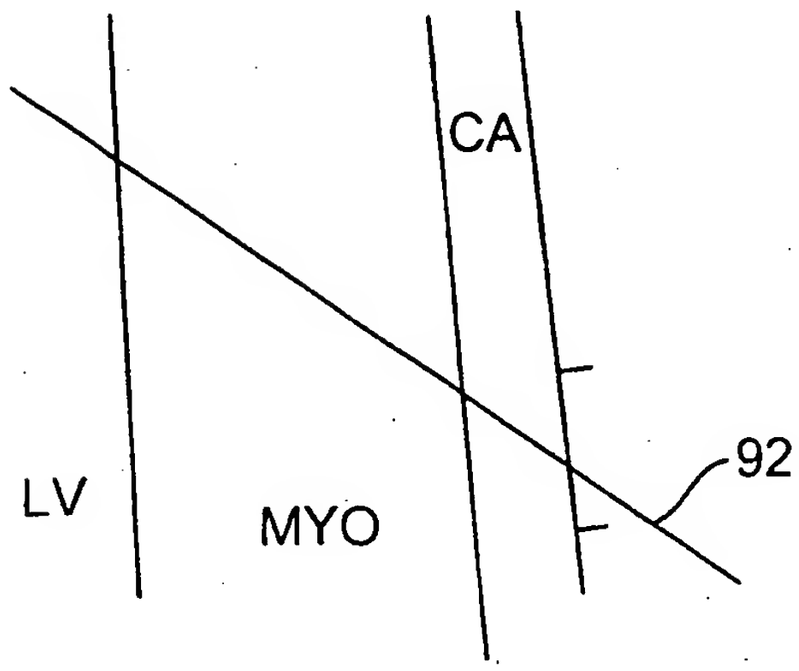

FIG. 12B

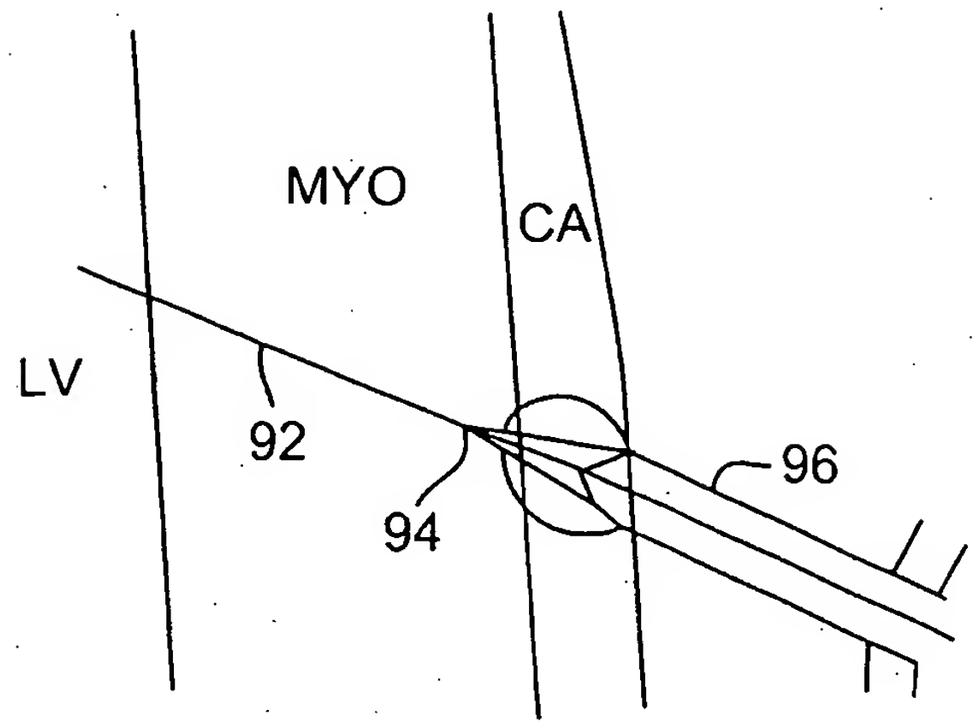

FIG. 12C

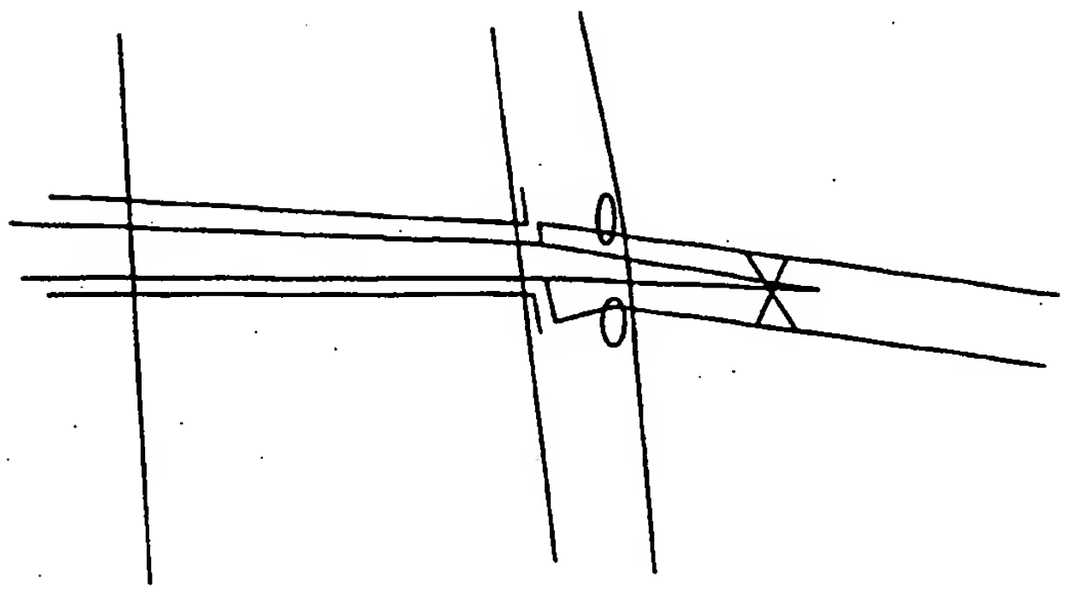

FIG. 12D

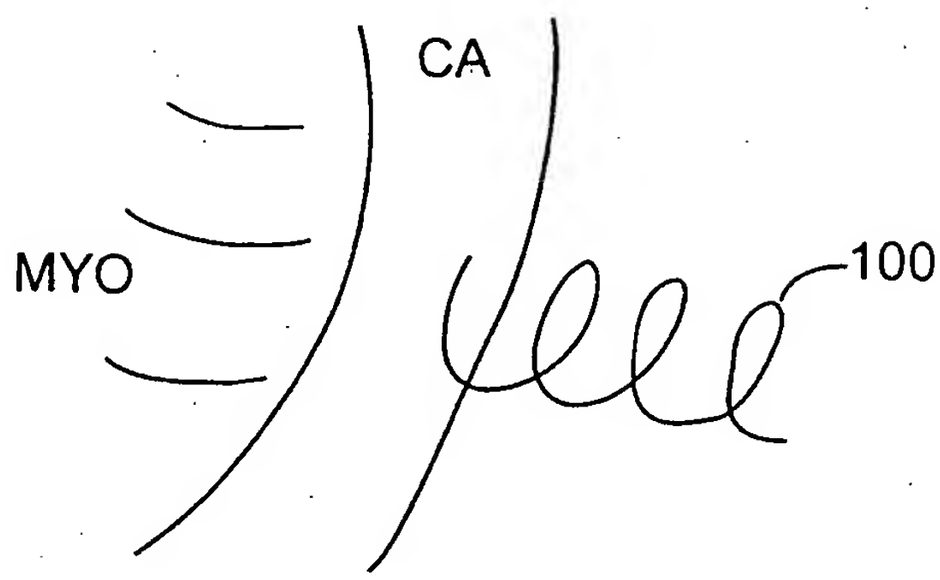

FIG. 13A

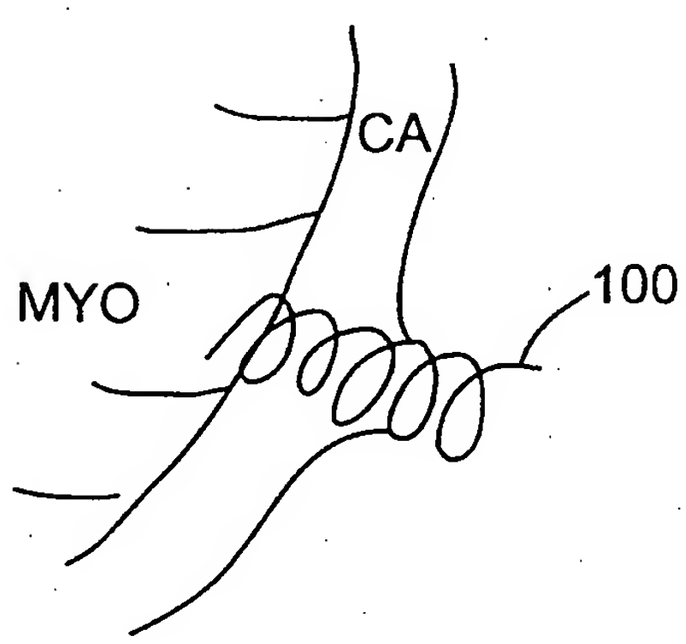

FIG. 13B

PULL OUT FORCES OF VARIOUS THREADED SCREWS

DESCRIPTION	THREADS PER INCH	HEIGHT OF THREADS	SHAFT DIAMETER	AVERAGE PULL OUT FORCE (LBS)
DRYWALL SCREW	15	0.023	0.093	1.80
DRYWALL SCREW	15	0.024	0.088	1.80
DRYWALL SCREW	8	0.028	0.122	1.75
HEX BOLT	30	0.015	0.132	<0.250
SHEET METAL SCREW	10	0.032	0.156	3.00

FIG. 14

PULL OUT FORCES OF BARBED SHUNTS

DESCRIPTION (ALL BARBS ARE ANNULAR)	NUMBER OF BARBS	BARB SPACING	BARB WIDTH (IN)	BARB DIAMETER	BARB HEIGHT (IN)	AVERAGE REMOVAL FORCE (LBS)
ANGLED BARBS FACING ONE DIRECTION	3	0.140	0.040	0.110	0.0065	0.38
CONTINUOUS ANGLED BARBS, NO SPACING BETWEEN EACH ONE	8	NONE	0.068	0.109	0.0055	0.42
ANGLED BARBS FACING ONE DIRECTION, FLANGE AT ONE END (TESTED IN DIFFERENT HEART)	6	NONE	0.085	0.108	0.0065	0.13
FLAT BARBS	4	0.062	0.049	0.108	0.0060	0.29
FLAT BARBS	2	0.140	0.054	0.110	0.0065	0.25
STENT ANGLED AT ONE END, FLAT BARBS, FLANGE AT OPPOSITE END (TESTED IN DIFFERENT HEART)	3	0.094	0.097	0.109	0.0035	<.13
CONTROL SAMPLE	NONE	NONE	NONE	NONE	NONE	~0
*ALL INSERTION FORCES ARE APPROXIMATELY 1.0 LB						
*THE APPROXIMATE WALL THICKNESS OF THE LEFT VENTRICLE IS .67-.84 IN, NEAR THE APEX OF THE HEART IT IS APPROXIMATELY .51 IN						

FIG. 15

PULL THROUGH FORCES FOR FLANGES THROUGH ARTERIAL WALL

DESCRIPTION	WIDTH (IN)	LENGTH (IN)	AVERAGE PULL THROUGH FORCE (LBS)
SHALLOW FLANGE, BARBED STENT, NO SPACES BETWEEN EACH BARB	0.114	0.169	0.50
SHALLOW FLANGE, FLAT BARBED STENT, OPPOSITE END ANGLED	0.097	0.132	0.50
DEEP FLANGE, FLAT STENT	0.108	0.159	1.00
VERY LONG AND DEEP FLANGE, FLAT STENT	0.109	0.195	1.50
FLAT STENT WITH ANGLED END, FLANGE TUBE SHAPED WITH OPENING IN THE MIDDLE	0.094	0.182	0.75
CIRCULAR FLANGE, FLAT STENT		0.169 R	0.75

FIG. 16

PCT/US00/21122

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US00/21122

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(25) Filing Language: English

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(30) Priority Data:
60/147,211 4 August 1999 (04.08.1999) US

(71) Applicant *(for all designated States except US)*: **PERCARDIA, INC.** [US/US]; Suite 202, 10 Al Paul Lane, Merrimak, NH 03054 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **GUILES, Marvin** [US/US]; 15 Heritage Lane, Stow, MA 01775 (US). **MELSKY, Gerald** [US/US]; 2 Dewey Road, Lexington, MA 02420 (US). **MCCABE, Margaret** [US/US]; 131 South Street, Apt. A, Waltham, MA 02453 (US).

(74) Agents: **GARRETT, Arthur, S.** et al.; Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., 1300 I Street, N.W., Washington, DC 20005-3315 (US).

(81) Designated States *(national)*: AU, CA, JP, US.

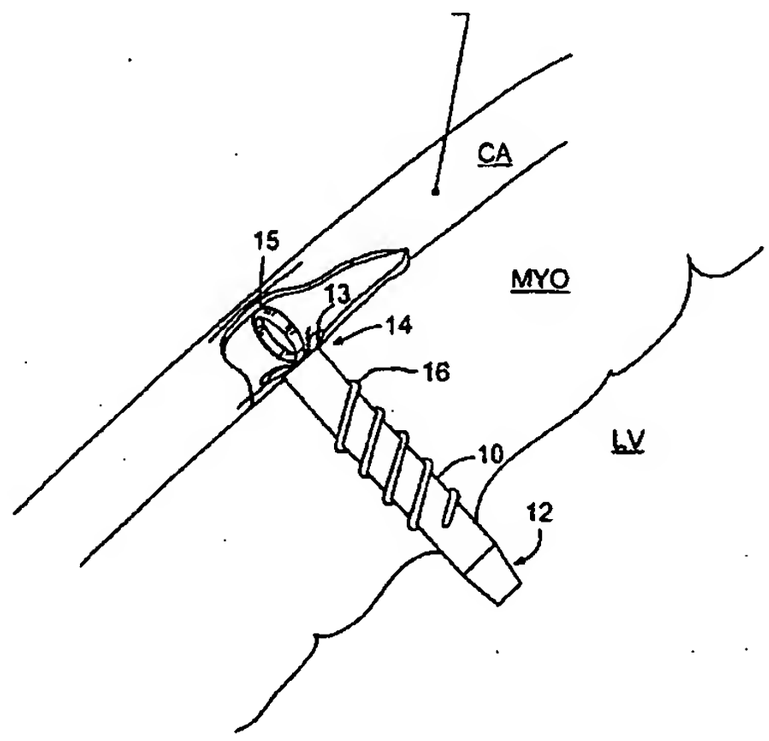
(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published:
— *with international search report*

(88) Date of publication of the international search report:
23 August 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: LEFT VENTRICULAR CONDUITS AND METHODS FOR DELIVERY



(57) Abstract: Conduits are provided to direct blood flow from the left ventricle to a coronary artery at a location distal to a blockage in the coronary artery. Threaded and nonthreaded conduits are delivered using a guidewire delivered through the posterior and anterior walls of a coronary artery and into the heart wall. A dilator may be provided over the guidewire into the heart wall, and the conduit delivered over the dilator. An introducer sleeve may be provided over the dilator into the heart wall, the dilator removed, and the conduit delivered through the introducer sleeve. A hollow needle also may be inserted into the posterior and anterior walls of the coronary artery prior to inserting the guidewire. A depth measuring tool may determine the appropriate length of the conduit prior to delivery. The depth measuring tool can include the hollow needle with an acces port on a proximal end of the needle and an opening on the distal end of the needle in flow communication with the access port so that when the needle is inserted through the heart wall and into the heart chamber, blood flow through the opening.

WO 01/10341 A3

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 00/21122

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 46115 A (TRANSVASCULAR, INC.) 22 October 1998 (1998-10-22)	1-5,7,8
Y	page 38, line 34 -page 40, line 2 page 44, line 31 -page 45, line 3 figures 5,8A	47

X	WO 97 32551 A (ENERGY LIFE SYSTEMS CORPORATION) 12 September 1997 (1997-09-12)	48
Y	page 5, line 15 - line 19; figure 3	47

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 November 2000	15. 03. 2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/21122

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 9-13,18-39
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-8,47,48

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-8,47,48

   A conduit for allowing the passage of blood

2. Claims: 14-17,40-46

   A device for measuring the depth of insertion/penetration into a heart.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ional Application No
PCT/US 00/21122

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9846115 A	22-10-1998	AU 6968698 A	11-11-1998
		EP 0981295 A	01-03-2000
WO 9732551 A	12-09-1997	US 5810836 A	22-09-1998
		EP 0891172 A	20-01-1999
		US 6080163 A	27-06-2000
		US 5971993 A	26-10-1999
		US 6053924 A	25-04-2000
		US 5878751 A	09-03-1999